



Clinical trial results:

A non-blinded retrospective biomarker add-on study to FIGARO-DKD for Bioprofiling the pharMacodynamic response to finerenone in FIGARO-DKD subjects (FIGARO-BM)

Summary

EudraCT number	2021-003053-37
Trial protocol	BG ES
Global end of trial date	31 December 2021

Results information

Result version number	v1 (current)
This version publication date	03 January 2023
First version publication date	03 January 2023

Trial information

Trial identification

Sponsor protocol code	21952
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05013008
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 September 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	31 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate long-term effect of finerenone treatment, in addition to standard-of-care, on circulating blood biomarkers associated with fibrosis, congestion, inflammation and vascular function

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 August 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 18
Country: Number of subjects enrolled	Belgium: 30
Country: Number of subjects enrolled	Denmark: 71
Country: Number of subjects enrolled	Finland: 27
Country: Number of subjects enrolled	Italy: 28
Country: Number of subjects enrolled	Netherlands: 9
Country: Number of subjects enrolled	Portugal: 6
Country: Number of subjects enrolled	Spain: 42
Country: Number of subjects enrolled	Sweden: 34
Country: Number of subjects enrolled	Bulgaria: 67
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Russian Federation: 83
Country: Number of subjects enrolled	Canada: 18
Country: Number of subjects enrolled	United States: 117
Country: Number of subjects enrolled	Hong Kong: 25
Country: Number of subjects enrolled	Israel: 62
Country: Number of subjects enrolled	Japan: 169

Country: Number of subjects enrolled	Singapore: 14
Country: Number of subjects enrolled	Korea, Republic of: 48
Country: Number of subjects enrolled	Taiwan: 61
Country: Number of subjects enrolled	Australia: 17
Worldwide total number of subjects	952
EEA total number of subjects	338

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	429
From 65 to 84 years	520
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

The study was conducted at multiple centers in 21 countries/regions between 18 August 2021 (first subject first visit) and 31 December 2021 (last subject last visit).

Pre-assignment

Screening details:

Overall, 952 subjects from previous FIGARO-DKD study (2015-000950-39) were screened for this FIGAGRO-BM study. Of them, 1 subject was a screening failure and 30 subjects missed treatment and/or biomarker data at Visit 3 or 11 in FIGARO-DKD. The remaining 921 subjects were included in the modified biomarker full analysis set of FIGAGRO-BM study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Finerenone

Arm description:

Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.

Arm type	Experimental
Investigational medicinal product name	Finerenone
Investigational medicinal product code	BAY94-8862
Other name	Kerendia
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet; starting at 10 mg or 20 mg; once daily; received in previous interventional Phase 3 trial FIGARO-DKD

Arm title	Placebo
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Arm description:

Participants received matching placebo once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Matching placebo; oral tablet; once daily; received in previous interventional Phase 3 trial FIGARO-DKD

Number of subjects in period 1 ^[1]	Finerenone	Placebo
Started	478	443
Completed	478	443

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: One (1) subject was screening failure and 30 subjects missed treatment and/or biomarker data at Visit 3 or 11 in FIGARO-DKD, therefore all of them were not included in the modified biomarker full analysis set of this FIGAGRO-BM study.

Baseline characteristics

Reporting groups

Reporting group title	Finerenone
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Reporting group description:

Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.

Reporting group title	Placebo
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Reporting group description:

Participants received matching placebo once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.

Reporting group values	Finerenone	Placebo	Total
Number of subjects	478	443	921
Age Categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	63.55	64.15	
standard deviation	± 9.50	± 9.65	-

Gender Categorical Units: Subjects			
Female	120	112	232
Male	358	331	689

Race Units: Subjects			
White	293	283	576
Black or African American	8	7	15
Asian	173	151	324
American Indian or Alaska Native	1	0	1
Native Hawaiian or Other Pacific Islander	0	1	1
Not Reported	1	1	2
Multiple	2	0	2

Plasma Matrilysin (P09237) level at Visit 3			
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The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=427;403

Units: Linear NPX (2 ^{NPX})			
geometric mean	19.618	18.956	
standard deviation	± 1.148	± 1.203	-

Plasma von Willebrand factor (P04275) level at Visit 3			
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The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434

Units: Linear NPX (2 ^{NPX})			
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geometric mean	3.200	2.338	
standard deviation	± 1.793	± 1.629	-
Plasma CCN family member 4 (O95388) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=470;436			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.600	1.578	
standard deviation	± 1.337	± 1.374	-
Plasma TGF beta-1 proprotein (P01137) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. TGF: Transforming growth factor. n=471;436			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.480	1.425	
standard deviation	± 1.327	± 1.349	-
Plasma TGF beta receptor type 3 (Q03167) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. TGF: Transforming growth factor. n=472;434			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.583	1.776	
standard deviation	± 1.631	± 1.624	-
Plasma IL-15 receptor subunit alpha (Q13261) at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. IL-15: Interleukin-15. n=435;408			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.678	1.614	
standard deviation	± 1.432	± 1.450	-
Plasma Metalloproteinase inhibitor 1 (P01033) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=432;408			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.818	1.824	
standard deviation	± 1.450	± 1.349	-
Plasma Pappalysin-1 (Q13219) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=435;408			
Units: Linear NPX (2 ^{NPX})			
geometric mean	0.171	0.164	
standard deviation	± 3.066	± 2.762	-
Plasma Protein AMBP (P02760) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit			

3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=470;436			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.595	1.611	
standard deviation	± 1.226	± 1.225	-
Plasma Proto-oncogene c-Src (P12931) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. Proto-oncogene c-Src: Proto-oncogene tyrosine-protein kinase Src. n=471;438			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.770	1.535	
standard deviation	± 2.614	± 2.229	-
Plasma Uromodulin (P07911) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=443;405			
Units: Linear NPX (2 ^{NPX})			
geometric mean	0.582	0.699	
standard deviation	± 1.752	± 1.531	-
Plasma Aminopeptidase N (P15144) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=461;433			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.224	1.248	
standard deviation	± 1.273	± 1.300	-
Plasma TNFRSF1A (P19438) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. TNFRSF1A: Tumor necrosis factor receptor superfamily member 1A. n=476;441			
Units: Linear NPX (2 ^{NPX})			
geometric mean	2.105	2.107	
standard deviation	± 1.606	± 1.575	-
Plasma CCN family member 2 (P29279) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=473;439			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.245	1.258	
standard deviation	± 1.585	± 1.360	-
Plasma PAI-1 (P05121) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. PAI-1: Plasminogen activator inhibitor 1. n=472;434			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.349	1.261	

standard deviation	± 2.148	± 1.868	-
Plasma uPAR (Q03405) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. uPAR: Urokinase plasminogen activator surface receptor. n=473;439			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.744	1.725	
standard deviation	± 1.699	± 1.398	-
Plasma C-C motif chemokine 14 (Q16627) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;441			
Units: Linear NPX (2 ^{NPX})			
geometric mean	3.013	3.056	
standard deviation	± 1.667	± 1.426	-
Plasma C-C motif chemokine 16 (O15467) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.625	1.633	
standard deviation	± 1.776	± 1.637	-
Plasma Collagen alpha-1(I) chain (P02452) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434			
Units: Linear NPX (2 ^{NPX})			
geometric mean	0.646	0.693	
standard deviation	± 1.675	± 1.497	-
Plasma Decorin (P07585) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=427;403			
Units: Linear NPX (2 ^{NPX})			
geometric mean	1.523	1.526	
standard deviation	± 1.233	± 1.233	-
Plasma C-C motif chemokine 2 (P13500) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=444;407			
Units: Linear NPX (2 ^{NPX})			
geometric mean	3.065	3.209	
standard deviation	± 1.285	± 1.367	-
Plasma Matrix metalloproteinase-9 (P14780) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=476;441			

Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	1.329 $\pm$ 2.202	1.176 $\pm$ 1.985	-
Plasma E-selectin (P16581) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434			
Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	1.235 $\pm$ 1.828	1.200 $\pm$ 1.577	-
Plasma Thrombospondin-2 (P35442) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=476;441			
Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	1.421 $\pm$ 1.655	1.452 $\pm$ 1.649	-
Plasma RARRES2 (Q99969) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. RARRES2: Retinoic acid receptor responder protein 2. n=472;441			
Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	2.201 $\pm$ 1.580	2.252 $\pm$ 1.418	-
Plasma C-X-C motif chemokine 16 (Q9H2A7) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434			
Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	1.341 $\pm$ 1.586	1.353 $\pm$ 1.338	-
Plasma Dickkopf-related protein 3 (Q9UBP4) level at Visit 3			
The protein concentration of biomarker levels was evaluated for 27 pre-defined plasma biomarkers. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. NPX is a unit on log2-scale that is logarithmically related to protein concentration. n=472;434			
Units: Linear NPX ($2^{\wedge}$ NPX) geometric mean standard deviation	1.827 $\pm$ 1.541	1.925 $\pm$ 1.460	-

End points

End points reporting groups

Reporting group title	Finerenone
Reporting group description: Subjects received finerenone 10 mg or 20 mg once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.	
Reporting group title	Placebo
Reporting group description: Participants received matching placebo once daily in addition to standard of care therapy in previous interventional Phase 3 trial FIGARO-DKD. No new intervention was administered in this biomarker study.	
Subject analysis set title	Modified biomarker full analysis set (mBFAS)
Subject analysis set type	Sub-group analysis
Subject analysis set description: All subjects with valid informed consent for this biomarker study (including both Study 21952 and the protocol addendum for FIGARO-DKD), which met the following criteria: a. Study enrollment criteria as defined in the study protocol. b. Analyzed biomarker samples at Visit 3 (4 months) and Visit 11 (36 months); Biomarker samples that were shipped at ambient temperatures were not analyzed. c. On Treatment at Visit 3 (4 months) and Visit 11 (36 months). "On treatment" was defined to include all participants who had not permanently discontinued the study treatment in FIGARO-DKD at Visit 3 or Visit 11. Study drug interruptions at these timepoints were not considered.	

Primary: Mean change in plasma biomarker levels after 36 months of treatment versus 4 months of treatment in a set of 27 pre-defined biomarkers

End point title	Mean change in plasma biomarker levels after 36 months of treatment versus 4 months of treatment in a set of 27 pre-defined biomarkers
End point description: The normalized protein expression (NPX) of biomarker levels were analyzed for the set of 27 pre-defined plasma biomarkers. NPX is a unit on log2-scale that is logarithmically related to protein concentration. Ratios of Visit 11 (36 months of treatment) to Visit 3 (4 months of treatment) were calculated to show the change in the plasma biomarker levels. Visit 3 (4 months of treatment) data were considered as baseline for the biomarker measurements as no pre-dose samples were available from FIGARO-DKD. TGF: Transforming growth factor; IL-15: Interleukin-15; Proto-oncogene c-Src: Proto-oncogene tyrosine-protein kinase Src; TNFRSF1A: Tumor necrosis factor receptor superfamily member 1A; PAI-1: Plasminogen activator inhibitor 1; uPAR: Urokinase plasminogen activator surface receptor; RARRES2: Retinoic acid receptor responder protein 2	
End point type	Primary
End point timeframe: At 4 months (Visit 3) of treatment and 36 months (Visit 11) of treatment	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	478 ^[1]	443 ^[2]		
Units: NPX				
number (not applicable)				
Matrilysin (P09237) n=387;386	0.020	0.086		
von Willebrand factor (P04275) n=466;429	-0.030	0.177		
CCN family member 4 (O95388) n=461;433	0.150	0.219		
TGF beta-1 proprotein (P01137) n=463;433	0.166	0.244		

TGF beta receptor type 3 (Q03167) n=466;429	0.180	0.292		
IL-15 receptor subunit alpha (Q13261) n=410;382	0.165	0.237		
Metalloproteinase inhibitor 1 (P01033) n=425;402	0.079	0.145		
Pappalysin-1 (Q13219) n=410;382	0.121	0.349		
Proto-oncogene c-Src (P12931) n=466;434	-0.111	-0.000		
Protein AMBP (P02760) n=461;433	0.049	0.063		
Uromodulin (P07911) n=437;400	-0.029	-0.065		
Aminopeptidase N (P15144) n=453;427	0.007	0.029		
TNFRSF1A (P19438) n=470;436	0.203	0.244		
PAI-1 (P05121) n=466;429	-0.082	-0.042		
CCN family member 2 (P29279) n=470;433	0.115	0.142		
uPAR (Q03405) n=470;433	0.150	0.173		
C-C motif chemokine 14 (Q16627) n=464;435	0.101	0.127		
C-C motif chemokine 16 (O15467) n=466;429	0.062	0.077		
Collagen alpha-1(I) chain (P02452) n=466;429	0.139	0.153		
Decorin (P07585) n=387;386	0.120	0.121		
C-C motif chemokine 2 (P13500) n=426;386	0.001	0.005		
Matrix metalloproteinase-9 (P14780) n=470;436	0.103	0.111		
E-selectin (P16581) n=466;429	0.013	0.014		
Thrombospondin-2 (P35442) n=470;436	0.077	0.079		
RARRES2 (Q99969) n=464;435	0.049	0.032		
C-X-C motif chemokine 16 (Q9H2A7) n=466;429	0.082	0.088		
Dickkopf-related protein 3 (Q9UBP4) n=466;429	0.070	0.077		

Notes:

[1] - mBFAS

[2] - mBFAS

Statistical analyses

Statistical analysis title	Matrilysin (P09237)
Statistical analysis description:	
The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[3]
P-value	= 0.001 ^[4]
Method	t-test, 2-sided

Notes:

[3] - The hypotheses 'H0i: $\beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i-th of the 27 pre-specified biomarkers.

Statistical analysis title	von Willebrand factor (P04275)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[5]
P-value	= 0.002 ^[6]
Method	t-test, 2-sided

Notes:

[5] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[6] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	CCN family member 4 (O95388)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[7]
P-value	= 0.044 ^[8]
Method	t-test, 2-sided

Notes:

[7] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[8] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	TGF beta-1 proprotein (P01137)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[9]
P-value	= 0.044 ^[10]
Method	t-test, 2-sided

Notes:

[9] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[10] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	TGF beta receptor type 3 (Q03167)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[11]
P-value	= 0.127 ^[12]
Method	t-test, 2-sided

Notes:

[11] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[12] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	IL-15 receptor subunit alpha (Q13261)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[13]
P-value	= 0.21 ^[14]
Method	t-test, 2-sided

Notes:

[13] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[14] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Metalloproteinase inhibitor 1 (P01033)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[15]
P-value	= 0.215 ^[16]
Method	t-test, 2-sided

Notes:

[15] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[16] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Pappalysin-1 (Q13219)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
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Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[17]
P-value	= 0.215 ^[18]
Method	t-test, 2-sided

Notes:

[17] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[18] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Proto-oncogene c-Src (P12931)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[19]
P-value	= 0.745 ^[20]
Method	t-test, 2-sided

Notes:

[19] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[20] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Protein AMBP (P02760)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[21]
P-value	= 0.762 ^[22]
Method	t-test, 2-sided

Notes:

[21] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[22] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Uromodulin (P07911)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[23]
P-value	= 0.762 ^[24]
Method	t-test, 2-sided

Notes:

[23] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[24] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Aminopeptidase N (P15144)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[25]
P-value	= 0.762 ^[26]
Method	t-test, 2-sided

Notes:

[25] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[26] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	TNFRSF1A (P19438)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[27]
P-value	= 0.762 ^[28]
Method	t-test, 2-sided

Notes:

[27] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[28] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Plasminogen activator inhibitor 1 (P05121)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[29]
P-value	= 0.917 ^[30]
Method	t-test, 2-sided

Notes:

[29] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[30] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	CCN family member 2 (P29279)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[31]
P-value	= 0.917 ^[32]
Method	t-test, 2-sided

Notes:

[31] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[32] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	uPAR (Q03405)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[33]
P-value	= 0.917 ^[34]
Method	t-test, 2-sided

Notes:

[33] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[34] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	C-C motif chemokine 14 (Q16627)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[35]
P-value	= 0.917 ^[36]
Method	t-test, 2-sided

Notes:

[35] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[36] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	C-C motif chemokine 16 (O15467)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
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Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[37]
P-value	= 0.979 ^[38]
Method	t-test, 2-sided

Notes:

[37] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[38] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Collagen alpha-1(I) chain (P02452)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[39]
P-value	= 0.979 ^[40]
Method	t-test, 2-sided

Notes:

[39] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[40] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Decorin (P07585)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[41]
P-value	= 0.979 ^[42]
Method	t-test, 2-sided

Notes:

[41] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[42] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	C-C motif chemokine 2 (P13500)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[43]
P-value	= 0.979 ^[44]
Method	t-test, 2-sided

Notes:

[43] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[44] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Matrix metalloproteinase-9 (P14780)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[45]
P-value	= 0.979 ^[46]
Method	t-test, 2-sided

Notes:

[45] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[46] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	E-selectin (P16581)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[47]
P-value	= 0.979 ^[48]
Method	t-test, 2-sided

Notes:

[47] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[48] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Thrombospondin-2 (P35442)
Statistical analysis description: The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.	
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[49]
P-value	= 0.979 ^[50]
Method	t-test, 2-sided

Notes:

[49] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,\dots,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[50] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	RARRES2 (Q99969)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[51]
P-value	= 0.979 ^[52]
Method	t-test, 2-sided

Notes:

[51] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[52] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	C-X-C motif chemokine 16 (Q9H2A7)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[53]
P-value	= 0.979 ^[54]
Method	t-test, 2-sided

Notes:

[53] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[54] - Adjusted using Benjamini-Hochberg Procedure

Statistical analysis title	Dickkopf-related protein 3 (Q9UBP4)
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Statistical analysis description:

The NPX differences (corresponding to log-transformed ratio to baseline) of biomarker levels were analyzed.

Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	921
Analysis specification	Pre-specified
Analysis type	other ^[55]
P-value	= 0.979 ^[56]
Method	t-test, 2-sided

Notes:

[55] - The hypotheses ' $H_{0i}: \beta_i=0$ ' ($i=1,...,27$) were tested at a two-sided significance level of 5%, where β_i was the estimator for the difference in log-transformed ratios of biomarker levels of Visit 11 to Visit 3 between finerenone and placebo group for the i -th of the 27 pre-specified biomarkers.

[56] - Adjusted using Benjamini-Hochberg Procedure

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

This was a retrospective, add-on biomarker study to the multi-center interventional Phase 3 study FIGARO-DKD (2015-000950-39). There were no study-specific safety assessments in this study. Safety of the subjects was monitored within the FIGARO-DKD study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This study was a retrospective, add-on biomarker study to the multi-center, interventional Phase 3 study FIGARO-DKD (2015-000950-39). There was no study-specific safety assessment in this study. Safety of the subjects was monitored within the FIGARO-DKD study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This study was a retrospective, add-on biomarker study to the multi-center, interventional Phase 3 study FIGARO-DKD (2015-000950-39). Blood plasma samples that were originally collected for PK analysis during the conduct of FIGARO-DKD study.

Notes: