Clinical trial results:
A multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled study to evaluate the efficacy and safety of finerenone compared to eplerenone on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction after recent heart failure decompensation and additional risk factors, either type 2 diabetes mellitus or chronic kidney disease or both.

Summary

EudraCT number	2015-002168-17
Trial protocol	SE DK IE CZ DE FI GB AT HU NL PT ES LT BG PL GR IT
Global end of trial date	11 March 2016

Results information

Result version number	v1 (current)
This version publication date	03 December 2019
First version publication date	03 December 2019
Summary attachment (see zip file)	Withdrawn Statement (Withdrawn Statement.pdf)

Trial information

Trial identification

Sponsor protocol code	BAY94-8862/16275

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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	11 March 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Demonstrate the superiority of finerenone to eplerenone in delaying time to first occurrence of the composite endpoint, defined as cardiovascular (CV) death or hospitalization for heart failure (HF), in patients with chronic heart failure (CHF) (NYHA class II–IV) and reduced ejection fraction after recent heart failure decompensation who have additional risk factors, i.e. type 2 diabetes mellitus (T2DM) and/or or chronic kidney disease (CKD).

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2016
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	Germany: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Overall Trial

Arm description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Arm type	Experimental
Investigational medicinal product name	BAY 94-8862 IR tablet 10 mg
Investigational medicinal product code	
Other name	Finerenone
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg finerenone tablet once daily (OD) in the morning OR 20 mg finerenone tablet OD in the morning

Investigational medicinal product name	BAY 94-8862 IR tablet 20 mg
Investigational medicinal product code	
Other name	Finerenone
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg finerenone tablet once daily (OD) in the morning OR 20 mg finerenone tablet OD in the morning

Number of subjects in period 1	Overall Trial
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial
Reporting group description:	
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.	

Reporting group values	Overall Trial	Total	
Number of subjects	99999	99999	
Age categorical			
Units: Subjects			
Age continuous			
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall Trial

Reporting group description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Primary: Time to the first occurrence of the primary composite endpoint, consisting of the following components: - Cardiovascular (CV) death - Hospitalization for Heart failure (HF)

End point title	Time to the first occurrence of the primary composite endpoint, consisting of the following components: - Cardiovascular (CV) death - Hospitalization for Heart failure (HF)[1]

End point description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

End point type	Primary

End point timeframe:

N/A

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No subjects were enrolled in the trial. Consequently, no results are available for this trial.

End point values	Overall Trial			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: 99999	99999			

Notes:

[2] - 99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

N/A

Adverse event reporting additional description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Overall Trial

Reporting group description:

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial.

Serious adverse events	Overall Trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Overall Trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No subjects were enrolled in the trial. Consequently, no results are available for this trial.

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.

99999 is "Not applicable" value or 0 subjects, this trial was discontinued with no subjects enrolled in the trial. Consequently, no results are available for this trial.

Notes: