



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-2115705

European Medicines Agency decision

EMA/PE/0000241538

of 16 May 2025

on the acceptance of a modification of an agreed paediatric investigation plan for finerenone (Kerendia) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



European Medicines Agency decision

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on the acceptance of a modification of an agreed paediatric investigation plan for finerenone (Kerendia) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0243/2021 issued on 9 July 2021 and the decision P/0365/2022 issued on 12 September 2022,

Having regard to the application submitted by Bayer AG on 18 December 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 March 2025, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for finerenone (Kerendia), are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0025/2015 issued on 30 January 2015, including subsequent modifications thereof.

Article 3

This decision is addressed to Bayer AG, 51368 - Leverkusen, Germany.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1894826

Amsterdam, 28 March 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000241538

Scope of the application

Active substance(s):

Finerenone

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of heart failure

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bayer AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted to the European Medicines Agency on 18 December 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0243/2021 issued on 9 July 2021 and the decision P/0365/2022 issued on 12 September 2022.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 27 January 2025.



Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified .

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

Waiver

Not applicable.

1. Paediatric investigation plan

1.1. Condition:

Treatment of heart failure

1.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with heart failure and reduced ejection fraction

1.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

1.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate formulation

1.1.4. Measures

Area	Description
Quality-related studies	Study 1 Development of an age-appropriate formulation (liquid or solid) for oral and enteral use of finerenone in newborns and infants.
Non-clinical studies	Study 2 Juvenile toxicity study of finerenone in rats.
Clinical studies	Study 3 Randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of finerenone as add-on to standard-of-care (SOC) treatment in paediatric patients from 6 months to less than 18 years of age with heart failure (HF) due to dilated cardiomyopathy or congenital heart disease (limited to biventricular physiology with systemic left ventricle (LV)). Study 4 Open-label extension study to evaluate the safety of finerenone as add-on to standard-of-care (SOC) treatment in paediatric patients from birth to less than 18 years of age with HF due to dilated cardiomyopathy or congenital heart disease.

Extrapolation, modelling and simulation studies	<p>Study 5</p> <p>Physiologically based pharmacokinetic (PBPK) analysis to determine paediatric dosing for finerenone in paediatric patients with HF.</p> <p>Study 6</p> <p>Population pharmacokinetic/pharmacodynamic (PopPKPD) analysis to support extrapolation of efficacy of finerenone in paediatric patients with HF.</p>
Other studies	Not applicable
Other measures	Not applicable

2. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s):

1. Treatment of chronic kidney disease

Authorised indication(s):

- Kerendia is indicated for the treatment of chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use