EMADOC-1700519818-2037384

European Medicines Agency decision

EMA/PE/0000235999

of 14 April 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

EMA/PE/0000235999

of 14 April 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

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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0025/2015 issued on 30 January 2015, the decision P/0362/2016 issued on 21 December 2016, the decision P/0160/2019 issued on 17 April 2019, the decision P/0324/2019 issued on 10 September 2019, the decision P/0298/2021 issued on 11 August 2021, the decision P/0434/2022 issued on 28 October 2022, and the decision P/0179/2023 issued on 17 May 2023,

Having regard to the application submitted by Bayer AG on 19 November 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the deferral.

[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), including changes to the deferral, 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 is addressed to Bayer AG, 51368 – Leverkusen, Germany.

EMADOC-1700519818-1804005
Amsterdam, 28 February 2025

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000235999

Scope of the application

Active substance(s):

Finerenone

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic kidney disease

Pharmaceutical form(s):

Film-coated tablet

Granules for oral suspension

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 19 November 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0025/2015 issued on 30 January 2015, the decision P/0362/2016 issued on 21 December 2016, the decision P/0160/2019 issued on 17 April 2019, the decision P/0324/2019 issued on 10 September 2019, the decision P/0298/2021 issued on 11 August 2021, the decision P/0434/2022 issued on 28 October 2022, and the decision P/0179/2023 issued on 17 May 2023.

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

The procedure started on 2 January 2025.

Scope of the modification

Some measures and timelines 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 and to the deferral 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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)

1. Waiver

1.1. Condition

Treatment of chronic kidney disease

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- film-coated tablet, granules for oral suspension, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of chronic kidney disease

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic kidney disease associated with proteinuria in addition to a therapy with angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB)

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

From 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Granules for oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of granules for oral suspension
Non-clinical studies	**Study 2** Juvenile toxicity study
Clinical studies	**Study 3** Relative bioavailability and food effect study of age-appropriate oral liquid formulation in adult healthy subjects

	Study 9 Relative bioavailability and food effect study of age-appropriate oral solid formulation in adult healthy subjects **Study 4** Randomized, double blind, placebo-controlled efficacy, safety and PK/PD study in children from 6 months to less than 18 years of age with chronic kidney disease (CKD) associated with proteinuria (FIONA (EudraCT Number: 2021-002071-19)) **Study 5** Open-label safety extension study in children from 1 year to less than 18 years of age with chronic kidney disease (CKD) associated with proteinuria
Extrapolation, modelling and simulation studies	**Study 6** Physiologically based PK modelling study to predict pharmacokinetics and to define the doses of finerenone for the paediatric clinical trial in children 6 months to less than 18 years of age with proteinuria associated with chronic kidney disease (CKD) **Study 7** Population PK-PD modelling study to characterise the pharmacokinetics and compare the expected and observed pharmacokinetics and pharmacodynamics in children 6 months to less than 18 years of age with proteinuria associated with CKD **Study 8** Extrapolation study to support exposure and efficacy assumptions in children 6 months to less than 18 years of age with proteinuria associated with CKD
Other studies	Not applicable
Other measures	Not applicable

3. 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 March 2029
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.
  - Invented name(s): Kerendia
  - Authorised pharmaceutical form(s): Film-coated tablet
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure