EMA/357803/2021

European Medicines Agency decision

P/0243/2021

of 9 July 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral for finerenone (EMEA-001623-PIP03-20) 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.

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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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Bayer AG on 20 April 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 May 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for finerenone, film-coated tablet, age-appropriate formulation, oral use, enteral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for finerenone, film-coated tablet, age-appropriate formulation, oral use, enteral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

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 4

This decision is addressed to Bayer AG, Kaiser-Wilhelm-Allee 1, 51368 - Leverkusen, Germany.

EMA/PDCO/154658/2021
Amsterdam, 21 May 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001623-PIP03-20

Scope of the application

Active substance(s):

Finerenone

Condition(s):

Treatment of heart failure

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate formulation

Route(s) of administration:

Oral use

Enteral use

Name/corporate name of the PIP applicant:

Bayer AG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted for agreement to the European Medicines Agency on 20 April 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 26 May 2020.

Supplementary information was provided by the applicant on 15 February 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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 annex 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of heart failure

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with heart failure and reduced ejection fraction

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**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	1	**Study 2** Juvenile toxicity study of finerenone in rats.
Clinical studies	2	**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. **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.

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	2	**Study 5** Physiologically based pharmacokinetic (PBPK) analysis to determine paediatric dosing for finerenone in paediatric patients with HF. **Study 6** Population pharmacokinetic/pharmacodynamic (PopPKPD) analysis to support extrapolation of efficacy of finerenone in paediatric patients with HF.
Other studies	0	Not applicable.
Other measures	0	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 July 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes