EMA/826903/2016

# European Medicines Agency decision

P/0362/2016

of 21 December 2016

on the acceptance of a modification of an agreed paediatric investigation plan for finerenone (EMEA-001623-PIP01-14-M01) 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 European Medicines Agency's decision P/0025/2015 issued on 30 January 2015,

Having regard to the application submitted by Bayer Pharma AG on 18 August 2016 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 11 November 2016, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for finerenone, film-coated tablet, age-appropriate oral (liquid or solid) dosage form , oral use, 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 Pharma AG, Müllerstraße 178, 13342 - Berlin, Germany.

EMA/PDCO/585569/2016
London, 11 November 2016

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

EMEA-001623-PIP01-14-M01

## Scope of the application

**Active substance(s):**

Finerenone

**Condition(s):**

Treatment of chronic kidney disease

**Pharmaceutical form(s):**

Film-coated tablet

Age-appropriate oral (liquid or solid) dosage form

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Bayer Pharma AG

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer Pharma AG submitted to the European Medicines Agency on 18 August 2016 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 13 September 2016.

## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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## 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 Norwegian Paediatric Committee member 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 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

## *1.1. Condition*

Treatment of chronic kidney disease

The waiver applies to:

- the paediatric population from birth to less than 6 months;
- film-coated tablet, oral use; age-appropriate oral (liquid or solid) dosage form; 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

Age appropriate oral (liquid or solid) dosage form

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 1 | **Study 1**<br>Development of an age-appropriate oral (liquid or solid) dosage form |
| Non-clinical studies | 1 | **Study 2**<br>Juvenile toxicity study |
| Clinical studies | 4 | **Study 3**<br>Relative bioavailability and food effect study of age appropriate oral liquid formulation in adult healthy subjects |

| | | |
|---|---|---|
| | | **Study 9**<br><br>Relative bioavailability and food effect study of age appropriate oral solid formulation in adult healthy subjects<br><br>**Study 4**<br><br>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<br><br>**Study 5**<br><br>Open-label safety extension study in children from 6 months to less than 18 years of age with chronic kidney disease (CKD) associated with proteinuria |
| Extrapolation, modelling and simulation studies | 3 | **Study 6**<br><br>Physiologically based PK modelling study to predict pharmacokinetics and to define the dose of finerenone in children 6 months to less than 18 years of age with proteinuria associated with chronic kidney disease (CKD)<br><br>**Study 7**<br><br>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<br><br>**Study 8**<br><br>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 September 2025 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |