EMA/137083/2017

European Medicines Agency decision

P/0070/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for vericiguat (EMEA-001636-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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on the acceptance of a modification of an agreed paediatric investigation plan for vericiguat (EMEA-001636-PIP01-14-M01) 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 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/0126/2015 issued on 5 June 2015,

Having regard to the application submitted by Bayer Pharma AG on 7 November 2016 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 27 January 2017, 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 vericiguat, tablet, age-appropriate oral solid formulation, 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/742650/2016
London, 27 January 2017

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

EMEA-001636-PIP01-14-M01

Scope of the application

Active substance(s):

Vericiguat

Condition(s):

Treatment of left ventricular failure

Pharmaceutical form(s):

Tablet

Age-appropriate oral solid formulation

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 7 November 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0126/2015 issued on 5 June 2015.

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

The procedure started on 29 November 2016.

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 Norwegian Paediatric Committee member 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 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 left ventricular failure

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic left ventricular failure with reduced ejection fraction in paediatric patients with dilated cardiomyopathies

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)

Tablet

Age-appropriate oral solid formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of new age-appropriate oral solid dosage form.
Non-clinical studies	2	**Study 2** Establishment of dose levels for definite juvenile toxicity study in rats (4-weeks study). **Study 3** Evaluation of systemic toxicity of vericiguat in juvenile rats (13-weeks study).
Clinical studies	3	**Study 4** Randomised parallel-group, placebo-controlled, double-blind, multi-centre trial to investigate PK, safety and efficacy of vericiguat in adolescents with dilated cardiomyopathy and chronic heart failure (CHF) (SOCCER 1).

		Study 5 Randomised parallel-group, placebo-controlled, double-blind, multi-centre trial to investigate PK, safety and efficacy of vericiguat in children with dilated cardiomyopathy and CHF (SOCCER 2). **Study 6** Relative bioavailability and food effect study in adult healthy subjects.
Extrapolation, modelling and simulation studies	1	**Study 7** PBPK modelling study to predict the PK properties in the paediatric population.
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:	No
Date of completion of the paediatric investigation plan:	By March 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes