EMA/300765/2015

European Medicines Agency decision

P/0126/2015

of 5 June 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral for vericiguat (EMEA-001636-PIP01-14) 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 Pharma AG on 11 August 2014 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 17 April 2015, in accordance with Article 18 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 vericiguat, tablet, age-appropriate oral liquid formulation, oral 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 vericiguat, tablet, age-appropriate oral liquid formulation, oral 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 is addressed to Bayer Pharma AG, Müllerstraße 178, 13342 - Berlin, Germany.

Done at London, 5 June 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/75140/2015
London, 17 April 2015

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

EMEA-001636-PIP01-14

Scope of the application

Active substance(s):

Vericiguat

Condition(s):

Treatment of left ventricular failure

Pharmaceutical form(s):

Tablet

Age-appropriate oral liquid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bayer Pharma AG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bayer Pharma AG submitted for agreement to the European Medicines Agency on 11 August 2014 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 16 September 2014.

Supplementary information was provided by the applicant on 16 January 2015. The applicant proposed modifications to the paediatric investigation plan.

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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 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Icelandic and the Norwegian Paediatric Committee members agree 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 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 liquid formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of new age-appropriate oral liquid 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