EMA/658961/2019

European Medicines Agency decision

P/0006/2020

of 6 January 2020

on the acceptance of a modification of an agreed paediatric investigation plan for sofosbuvir / velpatasvir / voxilaprevir (Vosevi), (EMEA-001822-PIP01-15-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/0121/2016 issued on 29 April 2016,

Having regard to the application submitted by Gilead Sciences Ireland UC on 8 August 2019 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 15 November 2019, 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 and to the waiver.

(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 and to the waiver.

[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 sofosbuvir / velpatasvir / voxilaprevir (Vosevi), film-coated tablet, age-appropriate oral dosage form, oral use, including changes to the deferral and to the waiver, 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 Gilead Sciences Ireland UC, Carrigtohill, T45 DP77 - County Cork, Ireland.

EMA/PDCO/465037/2019
Amsterdam, 15 November 2019

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

EMEA-001822-PIP01-15-M01

Scope of the application

Active substance(s):

Sofosbuvir / velpatasvir / voxilaprevir

Invented name:

Vosevi

Condition(s):

Treatment of chronic hepatitis C

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences Ireland UC

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences Ireland UC submitted to the European Medicines Agency on 8 August 2019 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/0121/2016 issued on 29 April 2016.

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

The procedure started on 17 September 2019.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver 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 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 hepatitis C

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- film-coated tablet, age-appropriate oral dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic hepatitis C

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of an age-appropriate oral solid dosage form for adolescents 12 to less than 18 years of age who are unable to swallow the adult-size tablets *Study 2: deleted in 001822-PIP01-15-M01.*
Non-clinical studies	0	Not applicable

Area	Number of measures	Description
Clinical studies	1	*Study 3: deleted in 001822-PIP01-15-M01.* **Study 4:** Open-label study to characterise the pharmacokinetics, safety, antiviral activity and efficacy of sofosbuvir (SOF) / velpatasvir (VEL) / voxilaprevir (VOX) fixed-dose combination (GS-US-367-1175)
Extrapolation, modelling and simulation studies	1	**Study 5:** Modelling and simulation study to leverage information gained in the SOF/VEL/VOX adult development program to guide the most appropriate model to describe paediatric PK (SOF/VEL/VOX Paediatric Exposures)
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 September 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of chronic hepatitis C

Authorised indication(s):

- Vosevi is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use