

EMA/90973/2017

European Medicines Agency decision

P/0066/2017

of 17 March 2017

on the acceptance of a modification of an agreed paediatric investigation plan for dasabuvir (sodium monohydrate) (Exviera), (EMA-001439-PIP01-13-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0314/2013 issued on 19 December 2013,

Having regard to the application submitted by AbbVie Ltd on 7 November 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 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 and to the deferral.
- (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.

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 dasabuvir (sodium monohydrate) (Exviera), tablet, age appropriate oral solid form, oral use, including changes to the deferral, 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 Abbvie Ltd, Abbvie House, Vanwall Road, SL6 4UB - Maidenhead, United-Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/757365/2016

London, 27 January 2017

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

EMA-001439-PIP01-13-M01

Scope of the application

Active substance(s):

Dasabuvir (sodium monohydrate)

Invented name:

Exviera

Condition(s):

Treatment of chronic hepatitis C

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Age appropriate oral solid form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AbbVie Ltd

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AbbVie Ltd submitted to the European Medicines Agency on 7 November 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/0314/2013 issued on 19 December 2013.

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

The procedure started on 29 November 2016.

Scope of the modification

Some measures and timelines 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 and to the deferral 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:

- children from birth to less than 3 years of age;
- for tablet and age-appropriate oral solid form, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Treatment of children and adolescents from 3 years to less than 18 years of age with genotype 1 chronic HCV infection and without liver decompensation, in combination with ombitasvir (OBV)/paritaprevir (PTV)/ ritonavir (RTV).

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

From 3 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Tablet, oral use.

Age-appropriate oral solid form, oral use.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1: Development of an appropriate oral solid form for children unable to swallow the adult tablet, including compatibility assessment.
Non-clinical	0	Not applicable.
Clinical	1	Measure 2: Open-label, single arm, PK/PD and tolerability study to assess the pharmacokinetics of OBV/PTV/RTV with dasabuvir (DSV) with or without RBV in treatment-naïve HCV Genotype 1-infected patients. <i>This study is the same as Measure 2 of the ombitasvir / paritaprevir / ritonavir PIP EMEA-001440-PIP01-13 and subsequent modifications thereof.</i> Measure 3: deleted in EMEA-001439-PIP01-13-M01

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2018
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):

- Exviera is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4 and 5.1).

For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use