EMA/415149/2020

European Medicines Agency decision

P/0356/2020

of 9 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for cenicriviroc (EMEA-001999-PIP02-17-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/0392/2018 issued on 7 December 2018,

Having regard to the application submitted by Allergan Pharmaceuticals International Limited on 20 April 2020 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 24 July 2020, 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 cenicriviroc, age-appropriate oral liquid dosage form, film-coated tablet, 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 Allergan Pharmaceuticals International Limited, Clonshaugh Business & Technology Park 17, Dublin, Ireland.

EMA/PDCO/232933/2020
Amsterdam, 24 July 2020

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

EMEA-001999-PIP02-17-M01

Scope of the application

Active substance(s):

Cenicriviroc

Condition(s):

Treatment of non-alcoholic steatohepatitis

Pharmaceutical form(s):

Age-appropriate oral liquid dosage form

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Allergan Pharmaceuticals International Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals International Limited submitted to the European Medicines Agency on 20 April 2020 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/0392/2018 issued on 7 December 2018.

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

The procedure started on 26 May 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The scope of the waiver has been extended.

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 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 non-alcoholic steatohepatitis (NASH)

The waiver applies to:

- the paediatric population from birth to less than 8 years of age;
- age-appropriate oral liquid dosage form, film-coated tablet, 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 non-alcoholic steatohepatitis (NASH)

2.1.1. Indication(s) targeted by the PIP

Treatment of liver fibrosis in children and adolescents from 8 to less than 18 years of age with NASH.

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

From 8 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Age-appropriate oral liquid dosage form

Film-coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	***Study 1*** *(study deleted as part of EMEA-001999-PIP02-17-M01)*
Non-clinical studies	0	***Study 2*** *(study deleted as part of EMEA-001999-PIP02-17-M01)*
Clinical studies	1	**Study 3** Double-blind, placebo controlled, dose selection, pharmacokinetic, efficacy and safety study in children and adolescents from 8 to <18 years with NASH. ***Study 4*** *(study deleted as part of EMEA-001999-PIP02-17-M01)*

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	1	**Study 5** Population pharmacokinetics modelling and simulation study.
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 August 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes