EMA/522035/2021

European Medicines Agency decision

P/0415/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for ozanimod (hydrochloride) (Zeposia), (EMEA-001710-PIP02-14-M06) 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/0198/2015 issued on 4 September 2015, decision P/0161/2017 issued on 30 June 2017, decision P/0345/2017 issued on 23 November 2017, and decision P/0325/2020 issued on 13 August 2020,

Having regard to the application submitted by Celgene Europe B.V. on 4 June 2021 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 10 September 2021, 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 ozanimod (hydrochloride) (Zeposia), capsule, hard, age-appropriate oral solid dosage 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 Celgene Europe B.V., Winthontlaan 6n, 3526 KV – Utrecht, The Netherlands.

EMA/PDCO/346238/2021
Amsterdam, 10 September 2021

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

EMEA-001710-PIP02-14-M06

Scope of the application

Active substance(s):

Ozanimod (hydrochloride)

Invented name:

Zeposia

Condition(s):

Treatment of multiple sclerosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Celgene Europe B.V.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Celgene Europe B.V. submitted to the European Medicines Agency on 4 June 2021 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/0198/2015 issued on 4 September 2015, decision P/0161/2017 issued on 30 June 2017, decision P/0345/2017 issued on 23 November 2017, and decision P/0325/2020 issued on 13 August 2020.

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

The procedure started on 12 July 2021.

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 multiple sclerosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- for capsule, hard and age-appropriate oral solid dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric investigation plan

2.1. Condition:

Treatment of multiple sclerosis

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and delay the accumulation of physical disability

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

From 10 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Capsule, hard

Age-appropriate oral solid 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
Non-clinical studies	2	**Study 2** 10-week juvenile rat toxicity study **Study 5** Added during procedure EMEA-001710-PIP02-14-M01 33-Day Oral Immunotoxicity Study in Juvenile Sprague-Dawley Rats

Clinical studies	1	**Study 3** Assessor-blind, randomised, active-controlled trial to evaluate safety and efficacy of ozanimod compared to interferon β-1ain children from 10 to less than 18 years of age with relapsing multiple sclerosis (RPC01-304)
Extrapolation, modelling and simulation studies	1	**Study 4** Development of a population PK / PD model to support the choice of dose in the safety and efficacy study in children from 10 to less than 18 years of age with relapsing multiple sclerosis
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 June 2025
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 multiple sclerosis

Authorised indication(s):

- Zeposia is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.

Authorised pharmaceutical form(s):

Hard capsule

Authorised route(s) of administration:

Oral use