EMA/488493/2020

European Medicines Agency decision

P/0383/2020

of 24 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for ozanimod (hydrochloride) (Zeposia), (EMEA-001710-PIP03-17-M02) 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/0153/2019 issued on 17 April 2019 and the decision P/0008/2020 issued on 3 January 2020,

Having regard to the application submitted by Celgene Europe B.V. on 29 May 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 4 September 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0198/2015 issued on 4 September 2015, including subsequent modifications thereof.

Article 3

This decision is addressed to Celgene Europe B.V., Winthontlaan 6n, 3526 KV – Utrecht, The Netherlands.

EMA/PDCO/322021/2020
Amsterdam, 4 September 2020

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

EMEA-001710-PIP03-17-M02

Scope of the application

Active substance(s):

Ozanimod (hydrochloride)

Invented name:

Zeposia

Condition(s):

Treatment of ulcerative colitis

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 29 May 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/0153/2019 issued on 17 April 2019 and the decision P/0008/2020 issued on 3 January 2020.

The application for modification proposed introduction of a cross reference to another agreed paediatric investigation plan for the same product.

The procedure started on 6 July 2020.

Scope of the modification

Introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in the condition treatment of ulcerative colitis, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0345/2017 dated 23 November 2017.

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 introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in condtion treatment of ulcerative colitis, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0345/2017 dated 23 November 2017.

   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

Treatment of ulcerative colitis (UC)

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- capsule, hard, age-appropriate oral solid 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 ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severely active ulcerative colitis

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

From 2 years 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	1	**Study 2** 33-Day oral immunotoxicity study in juvenile Sprague-Dawley rats
Clinical studies	4	**Study 3 (RPC01-3101)** Multicentre, randomized, double-blind, placebo-controlled study to evaluate safety and efficacy of ozanimod as induction and maintenance therapy for adolescents from 12 years to less than 18 years of age (and adults) with moderately to severely active ulcerative colitis.

		Study 4 (RPC01-3102) Open-label, multicentre, extension trial to evaluate the long-term safety and efficacy of ozanimod in adolescent patients from 12 years to less than 18 years of age (and adults) with moderately to severely active ulcerative colitis (UC) who have previously participated in an ozanimod trial, including study RPC01-3101. **Study 5 (UC-PED-PK)** Open-label pharmacokinetic study in children from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis. **Study 6 (UC-PED-PH3)** Safety and efficacy study with an open-label induction phase and a multicentre, randomised, double-blind, placebo controlled withdrawal period in children and adolescents from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis.
Extrapolation, modelling and simulation studies	1	**Study 7** Modelling and simulation study, to evaluate use of ozanimod in children from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis.
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 March 2026
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):

Treatment multiple sclerosis

Authorised indication(s):

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

Authorised pharmaceutical form(s):

Hard capsule

Authorised route(s) of administration:

Oral use