EMA/675386/2022

European Medicines Agency decision

P/0353/2022

of 11 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for apremilast (Otezla), (EMEA-000715-PIP05-13-M05) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0217/2014 issued on 3 September 2014, the decision P/0158/2017 issued on 29 June 2017, the decision P/0398/2018 issued on 6 December 2018 and the decision P/0389/2019 issued on 4 December 2019,

Having regard to the application submitted by Amgen Europe.B.V on 21 April 2022 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 22 July 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for apremilast (Otezla), tablet, oral suspension, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0171/2012 issued on 27 July 2012, including subsequent modifications thereof and all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0198/2012 issued on 24 August 2012, including subsequent modifications thereof.

Article 3

This decision is addressed to Amgen Europe.B.V, 7061 Minervum, 4817-ZK – Breda, The Netherlands.

EMA/PDCO/254620/2022
Amsterdam, 22 July 2022

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

EMEA-000715-PIP05-13-M05

Scope of the application

Active substance(s):

Apremilast

Invented name:

Otezla

Condition(s):

Treatment of Behçet's disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Amgen 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, Amgen Europe. B.V submitted to the European Medicines Agency on 21 April 2022 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/0217/2014 issued on 3 September 2014, the decision P/0158/2017 issued on 29 June 2017, the decision P/0398/2018 issued on 6 December 2018 and the decision P/0389/2019 issued on 4 December 2019.

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

The procedure started on 24 May 2022.

Scope of the modification

The timelines of the Paediatric Investigation Plan have been modified.

Opinion

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 Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

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 Behçet's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- tablet, oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of Behçet's disease

2.1.1. Indication(s) targeted by the PIP

Treatment of active oral ulcers (with or without concurrent genital ulcers) associated with Behçet's disease in patients who are candidates for systemic therapy.

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Oral suspension

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an oral formulation
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** (CC-10004-PBCT-001) Multi-centre, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and pharmacokinetics of apremilast in patients with Behçet's disease from 2 to less than 18 years of age.
Extrapolation, modelling and simulation studies	Not applicable

Other studies	Not applicable.
Other measures	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 December 2028
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 of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

Authorised indication(s):

Otezla, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.

Treatment of psoriasis

Authorised indication(s):

Otezla is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).

Treatment of Behcet's Disease

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet’s disease (BD) who are candidates for systemic therapy.

Authorised pharmaceutical form(s):

Tablet

Authorised route(s) of administration:

Oral use