EMA/792939/2015

European Medicines Agency decision

P/0300/2015

of 21 December 2015

on the acceptance of a modification of an agreed paediatric investigation plan for apremilast (Otezla) (EMEA-000715-PIP03-11-M03) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0300/2015

of 21 December 2015

on the acceptance of a modification of an agreed paediatric investigation plan for apremilast (Otezla) (EMEA-000715-PIP03-11-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0198/2012 issued on 24 August 2012 and the decision P/0139/2013 issued on 24 June 2013 and the decision P/0167/2015 issued on 7 August 2015,

Having regard to the application submitted by Celgene Europe Limited on 21 August 2015 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 13 November 2015, 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 apremilast (Otezla), tablet, oral liquid, 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 Limited, 1 Longwalk Road, Stockley Park, UB11 1DB - Uxbridge, United Kingdom.

Done at London, 21 December 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/692116/2015
London, 13 November 2015

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

EMEA-000715-PIP03-11-M03

Scope of the application

Active substance(s):

Apremilast

Invented name:

Otezla

Condition(s):

Treatment of psoriasis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Celgene Europe Limited

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Celgene Europe Limited submitted to the European Medicines Agency on 21 August 2015 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/0198/2012 issued on 24 August 2012 and the decision P/0139/2013 issued on 24 June 2013 and the decision P/0167/2015 issued on 7 August 2015.

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

The procedure started on 15 September 2015.

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 psoriasis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age;
- for tablet for oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of psoriasis

Treatment of moderate to severe psoriasis

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

From 6 to less than 18 years of age

2.1.2. Pharmaceutical form(s)

Tablet

Oral liquid

2.1.3. Measures

Area	Number of studies	Description
Quality related studies	0	Not applicable.
Non-clinical studies	1	**Study 1 CC-10004-TOX-1125** Toxicity study in mice during the entire developmental phase from weaning to adulthood
Clinical studies	2	**Study 2 CC-10004-PPSO-TBD1** Multicentre, open-label, non-controlled study to evaluate safety, palatability and pharmacokinetics in patients from 6 to less than 18 years with moderate to severe plaque psoriasis **Study 3 CC-10004-PPSO-TBD2** Multicentre, randomised, placebo-controlled, double-blinded study to evaluate efficacy and safety of apremilast in patients from 6 to less than 18 years with moderate to severe plaque psoriasis

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 July 2020
Deferral for one or more studies 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).

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use