EMA/332686/2013

European Medicines Agency decision

P/0139/2013

of 24 June 2013

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/0139/2013

of 24 June 2013

on the acceptance of a modification of an agreed paediatric investigation plan for apremilast (EMEA-000715-PIP03-11-M01) 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,

Having regard to the application submitted by Celgene Europe Limited on 20 February 2013 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 17 May 2013, 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 apremilast, tablet, 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 agreed PIP 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.

Article 3

This decision is addressed to Celgene Europe Limited, 1 Longwalk Road, Stockley Park, UB11 1DB Uxbridge, Middlesex, United Kingdom.

Done at London, 24 June 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/141588/2013

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

EMEA-000715-PIP03-11-M01

Scope of the application

Active substance(s):

Apremilast

Condition(s):

Treatment of psoriasis

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Celgene Europe Limited

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 20 February 2013 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.

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

The procedure started on 20 March 2013.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scope of the modification

The Paediatric Investigation Plan was linked to Paediatric Investigation Plan EMEA-000715-PIP-02-11.

Amendment of the scope of the Paediatric Investigation Plan to include another condition.

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 in the scope set out in the Annex I of this opinion.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subsets of the paediatric population and conditions 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.

London, 17 May 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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 for oral use.

2.1.3. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical	1	Study 1) CC-10004-TOX-1125 Toxicity study in mice during the entire developmental phase from weaning to adulthood.
Clinical	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 January 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes