EMA/392184/2014

# European Medicines Agency decision

P/0166/2014

of 8 July 2014

on the acceptance of a modification of an agreed paediatric investigation plan for apremilast (EMEA-000715-PIP02-11-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.**

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# European Medicines Agency decision

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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/0171/2012 issued on 27 July 2012,

Having regard to the application submitted by Celgene Europe Limited on 28 February 2014 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 23 May 2014, 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 liquid, 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 is addressed to Celgene Europe Limited, 1 Longwalk Road, Stockley Park, UB11 1DB - Uxbridge, Middlesex, United Kingdom.

Done at London, 8 July 2014

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

EMA/PDCO/176028/2014

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

EMEA-000715-PIP02-11-M01

## Scope of the application

**Active substance(s):**

Apremilast

**Condition(s):**

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

**Pharmaceutical form(s):**

Tablet

Oral liquid

**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 28 February 2014 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/0171/2012 issued on 27 July 2012.

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

The procedure started on 25 March 2014.

## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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## 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 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 annex and appendix.

London, 23 May 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

# 1. Waiver

## *1.1. Condition*

### *Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)*

The waiver applies to:

- children from birth to less than 1 year of age;
- for tablet, oral liquid, for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);
- children from 1 year to less than 2 years of age;
- for tablet, oral liquid, for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

# 2. Paediatric Investigation Plan

## *2.1. Condition*

### *Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)*

Treatment of juvenile idiopathic arthritis

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

From 2 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 | 1 | Study 1<br>Development of oral liquid for paediatric use. |
| Non-clinical studies | 1 | Study 2<br>CC-10004-TOX-1125 |

| Area | Number of studies | Description |
|---|---|---|
| | | Toxicity study in mice during the entire developmental phase from weaning to adulthood. |
| Clinical sudies | 3 | Study 3<br>Open-label pharmacokinetic and safety study in children with juvenile idiopathic arthritis (JIA) from 6 to less than 18 years of age.<br>Study 4<br>Open-label pharmacokinetic and safety study in children with JIA with 50 weeks open label extension.<br>Study 5<br>Double-blind, randomised placebo-controlled study to evaluate safety and efficacy in children with JIA with open label extension phase. |

## 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 November 2018 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |