EMA/280412/2014

European Medicines Agency decision

P/0144/2014

of 13 June 2014

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457) (EMEA-000380-PIP01-08-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/0144/2014

of 13 June 2014

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457) (EMEA-000380-PIP01-08-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/154/2009 issued on 11 August 2009,

Having regard to the application submitted by Novartis Europharm Ltd on 31 January 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 25 April 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 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 recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457), powder for solution for injection, solution for injection, subcutaneous 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 Novartis Europharm Ltd, Wimblehurst Road, RH12 5AB - Horsham, United Kingdom.

Done at London, 13 June 2014

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

EMA/PDCO/67906/2014

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

EMEA-000380-PIP01-08-M01

Scope of the application

Active substance(s):

Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457)

Condition(s):

Treatment of psoriasis vulgaris

Pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd submitted to the European Medicines Agency on 31 January 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/154/2009 issued on 11 August 2009.

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

The procedure started on 26 February 2014.

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

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 annex and appendix.

London, 25 April 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

1. Waiver

1.1. Condition: treatment of psoriasis

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- for powder for solution for injection for subcutaneous 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).

2. Paediatric Investigation Plan

2.1. Condition: treatment of psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to non-biologic systemic therapies

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

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

Solution for injection (pre-filled syringe or pen)

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies		Not applicable.
Non-clinical studies	2	Study 1. Fertility and early embryonic development (FEED) study in mice using a surrogate antibody. Study 2. Peri- and postnatal study in mice using a surrogate antibody.
Clinical studies	2	Study 3. CAIN457A2310 Double-blind, randomized, placebo-controlled, active comparator (etanercept as single-blinded arm) multicentre trial with secukinumab in children from 6 to less than 18 years of age with severe plaque psoriasis to demonstrate the efficacy of secukinumab as compared to placebo and compared to etanercept

Area	Number of studies	Description
		Study 4. Double-blind, placebo-controlled multicentre trial with secukinumab in children from 6 to less than 18 years of age with moderate plaque psoriasis to demonstrate the efficacy of secukinumab as compared to placebo

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes