EMA/3164/2016

European Medicines Agency decision

P/0003/2016

of 15 January 2016

on the acceptance of a modification of an agreed paediatric investigation plan for ustekinumab (Stelara) (EMEA-000311-PIP01-08-M04) 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 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/19/2009 issued on 4 February 2010, and the decision P/180/2010 issued on 24 September 2010 and the decision P/0226/2012 issued on 3 October 2012,

Having regard to the application submitted by Janssen-Cilag International NV on 18 September 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 11 December 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 ustekinumab (Stelara), 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 Janssen-Cilag International NV, Turnhoutseweg 30, B2340 – Beerse, Belgium.

Done at London, 15 January 2016

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

EMA/PDCO/686481/2015
London, 11 December 2015

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

EMEA-000311-PIP01-08-M04

Scope of the application

Active substance(s):

Ustekinumab

Invented name:

Stelara

Condition(s):

Treatment of chronic plaque psoriasis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 18 September 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/19/2009 issued on 4 February 2010, and the decision P/180/2010 issued on 24 September 2010 and the decision P/0226/2012 issued on 3 October 2012.

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

The procedure started on 13 October 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 chronic plaque psoriasis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 6 years;
- for solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: treatment of chronic plaque psoriasis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severe chronic plaque psoriasis that cannot be adequately controlled with topical therapy and/or phototherapy.

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

From 6 years to less than 18 years.

2.1.3. Pharmaceutical form(s)

Solution for injection, subcutaneous use.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical	4	Study 1 1 month repeated-dose toxicology study with intravenous ustekinumab in juvenile monkeys. Study 2 26 week (with 13 week interim sacrifice) repeated-dose toxicology study with subcutaneous ustekinumab in juvenile monkeys. Study 3 18 day local tolerance and pharmacokinetic study with ustekinumab in juvenile monkeys.

		Study 4 Combined embryofoetal development / pre- and postnatal development study of ustekinumab in monkeys (gestation day 20 – lacation day 33, exposure of neonates for 6 months).
Clinical	2	Study 5 Randomised, double-blind, placebo-controlled, multicentre trial to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of ustekinumab in children aged from 12 to less than 18 years with moderate to severe chronic plaque psoriasis. Study 6 Open-label, multicentre trial to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of ustekinumab in children aged from 6 to less than 12 years with moderate to severe chronic plaque psoriasis.
Extrapolation, modelling and simulation studies	1	Study 7 Modelling and Simulation Analysis
Other studies	0	
Other measures	0	

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 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):

1. Treatment of psoriasis

Authorised indication(s):

Plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A).

Paediatric plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

Psoriatic arthritis (PsA)

STELARA, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Authorised pharmaceutical form(s):

Solution for injection

Solution for injection in pre-filled syringe

Authorised route(s) of administration:

Subcutaneous use