EMA/576874/2020

European Medicines Agency decision

P/0467/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for ustekinumab (Stelara), (EMEA-000311-PIP03-11-M06) 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.

European Medicines Agency decision

P/0467/2020

of 1 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for ustekinumab (Stelara), (EMEA-000311-PIP03-11-M06) 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/0062/2012 issued on 28 March 2012, the decision P/0292/2012 issued on 18 December 2012 and the decision P/0109/2017 issued on 11 April 2017,

Having regard to the application submitted by Janssen-Cilag International NV on 10 July 2020 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 16 October 2020, 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 and to the waiver.

(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 and to the waiver.

[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, solution for injection (in pre-filled syringe), concentrate for solution for infusion, subcutaneous use, intravenous use, including changes to the deferral and to the waiver, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/19/2009 issued on 4 February 2009, in the decision P/0045/2014 issued on 7 March 2014 and in the decision P/019/2018 issued on 17 July 2019 including subsequent modifications thereof.

Article 3

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, B2340 - Beerse, Belgium.

EMA/PDCO/417749/2020
Amsterdam, 16 October 2020

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

EMEA-000311-PIP03-11-M06

Scope of the application

Active substance(s):

Ustekinumab

Invented name:

Stelara

Condition(s):

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

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Solution for injection (in pre-filled syringe)

Concentrate for solution for infusion

Route(s) of administration:

Subcutaneous use

Intravenous 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 10 July 2020 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/0062/2012 issued on 28 March 2012, the decision P/0292/2012 issued on 18 December 2012 and the decision P/0109/2017 issued on 11 April 2017.

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

The procedure started on 18 August 2020.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a paediatric subset has been removed.

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 and to the waiver 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 idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- children from birth to less than 2 years of age;
- solution for injection, solution for injection (in pre-filled syringe), concentrate for solution for infusion, subcutaneous use intravenous 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);

And

- children from 2 to less than 5 years of age;
- solution for injection, solution for injection (in pre-filled syringe), concentrate for solution for infusion, subcutaneous use, intravenous 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 idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis (JIA)

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

From 5 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

Solution for injection (in pre-filled syringe)

Concentrate for solution for infusion

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of age-appropriate strength for children less than 12 years of age.
Non-clinical	0	Not applicable.
Clinical	1	***Study 2*** *removed in Modification of an agreed PIP EMEA-000311-PIP03-11-M06.* ***Study 3*** *removed in Modification of an agreed PIP EMEA-000311-PIP03-11-M02.* **Study 4** *added in Modification of an agreed PIP EMEA-000311-PIP03-11-M06.* Multicentre, open-label study to evaluate the efficacy, pharmacokinetics and safety of ustekinumab in paediatric patients from 5 years of age to less than 18 years of age with juvenile psoriatic arthritis (CNTO1275JPA3001)
Extrapolation, modelling and simulation studies	2	**Study 5** *added in Modification of an agreed PIP EMEA-000311-PIP03-11-M06.* Modelling and simulation study to characterize the pharmacokinetics of ustekinumab in children from 5 to less than 18 years of age with juvenile psoriatic arthritis (jPsA) and to evaluate the covariates that affect PK exposure. **Study 6** *added in Modification of an agreed PIP EMEA-000311-PIP03-11-M06.* Extrapolation study to evaluate the use of ustekinumab in patients from 5 to less than 18 years of age with juvenile psoriatic arthritis.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2026
Deferral for one or more measures 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:

- 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).
- STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

2. Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Authorised indication:

- 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 to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate

3. Treatment of Crohn's disease

Authorised indication:

- STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies.

4. Treatment of ulcerative colitis

Authorised indication:

- STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

Authorised pharmaceutical formulation(s):

Concentrate for solution for infusion

Solution for injection

Solution for injection in pre-filled syringe

Authorised route(s) of administration:

Intravenous use

Subcutaneous use