EMA/68373/2022

European Medicines Agency decision

P/0065/2022

of 11 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for guselkumab (Tremfya), (EMEA-001523-PIP05-19-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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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0293/2020 issued on 12 August 2020,

Having regard to the application submitted by Janssen-Cilag International N.V. on 14 October 2021 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 21 January 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for guselkumab (Tremfya), solution for injection, solution for injection in pre-filled syringe, solution for injection in pre-filled pen, intravenous use, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0073/2016 issued on 18 March 2016, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/604627/2021 corr
Amsterdam, 21 January 2022

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

EMEA-001523-PIP05-19-M01

Scope of the application

Active substance(s):

Guselkumab

Invented name:

Tremfya

Condition(s):

Treatment of Crohn's Disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Solution for injection in pre-filled syringe

Solution for injection in pre-filled pen

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Janssen-Cilag International N.V.

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 N.V. submitted to the European Medicines Agency on 14 October 2021 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/0293/2020 issued on 12 August 2020.

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

The procedure started on 22 November 2021.

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 Crohn's Disease

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for injection in pre-filled pen, solution for injection in pre-filled syringe, solution for injection, 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 Crohn's Disease

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active Crohn's disease in paediatric subjects from 2 to less than 18 years of age with, who have had an inadequate response, lost response, or were intolerant to either conventional therapy or biologic therapy

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled pen

Solution for injection in pre-filled syringe

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1 (CNTO1959PBCRD3007)** Randomised, open-label induction treatment period in which patients receive intravenous (IV) or subcutaneous (SC) guselkumab induction dosing, followed by a

		randomized, double-blind, 2-arm maintenance treatment period in which all patients receive SC guselkumab dosing (two different dose levels) to assess pharmacokinetics (PK), efficacy, and safety in paediatric subjects from 2 to less than 18 years of age with moderately to severely active Crohn's disease.
Extrapolation, modelling and simulation studies	2	**Study 2** Extrapolation/interpolation population PK model **Study 3** Extrapolation/interpolation exposure response model
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:	No
Date of completion of the paediatric investigation plan:	By January 2028
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(s):

- Tremfya is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Authorised pharmaceutical form(s):

Solution for injection in pre-filled syringe

Solution for injection in pre-filled pen

Authorised route(s) of administration:

Subcutaneous use