EMA/83632/2018

European Medicines Agency decision

P/0065/2018

of 16 March 2018

on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi), (EMEA-000265-PIP02-11-M02) 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/0106/2012 issued on 8 June 2012 and the decision P/0073/2014 issued on 2 April 2014,

Having regard to the application submitted by Janssen Biologics B.V. on 6 November 2017 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 26 January 2018, 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 golimumab (Simponi), 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 Biologics B.V., Einsteinweg 101, 2333 CB - Leiden, The Netherlands.

EMA/PDCO/739823/2017
London, 26 January 2018

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

EMEA-000265-PIP02-11-M02

Scope of the application

Active substance(s):

Golimumab

Invented name:

Simponi

Condition(s):

Treatment of ulcerative colitis

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 Biologics B.V.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen Biologics B.V. submitted to the European Medicines Agency on 6 November 2017 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/0106/2012 issued on 8 June 2012 and the decision P/0073/2014 issued on 2 April 2014.

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

The procedure started on 28 November 2017.

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 ulcerative colitis

The waiver applies to:

- children from birth to less than 2 years of age;
- solution for injection, 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 ulcerative colitis

2.1.1 Indication(s) targeted by the PIP

Treatment of ulcerative colitis

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

From 2 to less than 18 years of age

2.1.3 Pharmaceutical form(s)

Solution for injection

2.1.4 Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1:** Development of an age-appropriate paediatric presentation
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2:** A multicentre, open-label study to assess the PK and safety of golimumab treatment in patients from 2 to less than 18 years old with moderately to severely active ulcerative colitis. **Study 3 deleted during procedure EMEA 000265-PIP02-11-M02**

Area	Number of studies	Description
		Study 4 (added during procedure EMEA 000265-PIP02-11-M02) Randomised, open-label golimumab study in paediatric patients from 2 to less than 18 years with moderately to severely active ulcerative colitis.
Extrapolation, modelling and simulation studies	3	**Study 5** (added during procedure EMEA 000265-PIP02-11-M02) Population pharmacokinetic (PK) modelling and simulation study. **Study 6** (added during procedure EMEA 000265-PIP02-11-M02) Exposure-response modelling and simulation study. **Study 7** (added during procedure EMEA 000265-PIP02-11-M02) Analysis of internal and literature data to support the assumptions of similarity of disease, treatment effects, and exposure-response relationship between pediatric and adult subjects with ulcerative colitis (UC)
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 December 2024
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 rheumatoid arthritis (RA)

Authorised indication(s):

Simponi, in combination with methotrexate (MTX), is indicated for

- the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX.

Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

2. Treatment of polyarticular juvenile idiopathic arthritis (pJIA)

Simponi in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX.

3. Treatment of psoriatic arthritis (PsA)

Authorised indication:

Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

4. Treatment of ankylosing spondylitis (AS)

Authorised indication:

Simponi is indicated for the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

5. Treatment of non-radiographic axial spondyloarthritis (nr-Axial SpA)

Simponi is indicated for the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

6. Treatment of ulcerative colitis (UC)

Simponi is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Authorised pharmaceutical form(s):

Solution for injection in prefilled pen, solution for injection in prefilled syringe.

Authorised route(s) of administration:

Subcutaneous use