EMA/698393/2013

European Medicines Agency decision

P/0309/2013

of 19 December 2013

on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi), (EMEA-000265-PIP01-08-M03) 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/58/2010 issued on 26 March 2010, the decision P/84/2010 issued on 1 June 2010, and the decision P/197/2011 issued on 30 August 2011,

Having regard to the application submitted by Janssen Biologics B.V. on 16 August 2013 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 8 November 2013, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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, solution for infusion, subcutaneous use, intravenous use, 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 (P.O. Box 251) 2333 CB - Leiden, The Netherlands.

Done at London, 19 December 2013

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

EMA/PDCO/543658/2013 Corr

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

EMEA-000265-PIP01-08-M03

Scope of the application

Active substance(s):

Golimumab

Invented name:

Simponi

Condition(s):

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

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Solution for infusion

Route(s) of administration:

Subcutaneous use

Intravenous 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 16 August 2013 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/58/2010 issued on 26 March 2010, the decision P/84/2010 issued on 1 June 2010, and the decision P/197/2011 issued on 30 August 2011.

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

The procedure started on 12 September 2013.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. Name of the condition has been changed.

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 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.

London, 8 November 2013

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 chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

The waiver applies to:

- children from birth to less than 2 years;
- for the solution for injection for subcutaneous use, and for the solution for infusion for intravenous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of children with moderately to severely active polyarticular-course juvenile idiopathic arthritis (defined as one of: rheumatoid factor positive or negative polyarticular JIA , systemic JIA with no systemic symptoms but with polyarthritis , extended oligoarticular JIA, or polyarticular juvenile psoriatic arthritis) in combination with methotrexate, in whom the response to methotrexate has been inadequate

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

From 2 years to less than 18 years

2.1.3. Pharmaceutical form(s)

Solution for injection

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1 Solution for injection for subcutaneous use in age-appropriate pre-filled syringe
Non-clinical		Not applicable.

Clinical	1	Measure 2 Double-blind, randomised withdrawal, multi-centre; two phase placebo controlled study to evaluate pharmacokinetics, safety and efficacy of golimumab in combination with methotrexate in children with JIA from 2 years to less than 18 years of age with inadequate response to methotrexate

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 August 2014
Deferral for some or all 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 rheumatoid arthritis

   Authorised indications:

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

   - treatment of moderate to severe, active rheumatoid arthritis in patients when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate.
   - treatment of severe, active and progressive rheumatoid arthritis in patients 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 psoriatic arthritis

   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 (see section 5.1) and to improve physical function.

3. Treatment of ankylosing spondylitis

   Authorised indication:

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

Authorised pharmaceutical form(s):

Solution for injection in pre-filled pen

Solution for injection in pre-filled syringe

Authorised route(s) of administration:

Subcutaneous use