EMA/468298/2014

# European Medicines Agency decision

P/0226/2014

of 5 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi), (EMEA-000265-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/58/2010 issued on 26 March 2010, the decision P/84/2010 issued on 1 June 2010, the decision P/197/2011 issued on 30 August 2011, and the decision P/0309/2013 issued on 19 December 2013,

Having regard to the application submitted by Janssen Biologics BV on 10 April 2014 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 18 July 2014, 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, solution for infusion, subcutaneous use, intravenous 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 BV, Einsteinweg 101, 2333 CB – Leiden, The Netherlands.

Done at London, 5 September 2014

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

EMA/PDCO/258240/2014 Corr

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

EMEA-000265-PIP01-08-M04

## 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 BV

**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 BV submitted to the European Medicines Agency on 10 April 2014 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, the decision P/197/2011 issued on 30 August 2011, and the decision P/0309/2013 issued on 19 December 2013.

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

The procedure started on 21 May 2014.

A meeting with the Paediatric Committee took place on 16 July 2014.

## 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.

London, 18 July 2014

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 (PIP)

# 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;
- solution for injection, subcutaneous use; solution for infusion, 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 | | Not applicable. |
| Non-clinical | | Not applicable. |

| | | |
|---|---|---|
| Clinical | 1 | Measure 1<br><br>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 March 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.

4. Treatment of Ulcerative colitis

   Authorised indication:

   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 pre-filled pen

Solution for injection in pre-filled syringe

## Authorised route(s) of administration:

Subcutaneous use