EMA/354076/2012

# European Medicines Agency decision

P/0106/2012

of 8 June 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for golimumab (Simponi) (EMEA-000265-PIP02-11) 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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# European Medicines Agency decision

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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 application submitted by Janssen Biologics B.V. on 5 August 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 May 2012, in accordance with Article 18 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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a 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***

A paediatric investigation plan for golimumab (Simponi), solution for injection in pre-filled syringe, solution for injection in pre-filled pen, concentrate for solution for infusion, subcutaneous use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

***Article 2***

A deferral for golimumab (Simponi), solution for injection in pre-filled syringe, solution for injection in pre-filled pen, concentrate for solution for infusion, subcutaneous use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 3***

A waiver for golimumab (Simponi), solution for injection in pre-filled syringe, solution for injection in pre-filled pen, concentrate for solution for infusion, subcutaneous use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 4**

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as granted in the decision P/58/2010 issued on 26 March 2010, including subsequent modifications thereof.

***Article 5***

This decision is addressed to Janssen Biologics B.V., Einsteinweg 101 (P.O. Box 251), 2333 CB - Leiden, The Netherlands.

Done at London, 8 June 2012

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

EMA/354076/2012

# Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000265-PIP02-11

## 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 in pre-filled syringe

Solution for injection in pre-filled pen

Concentrate for 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 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen Biologics B.V. submitted for agreement to the European Medicines Agency on 5 August 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 14 September 2011.

Supplementary information was provided by the applicant on 23 February 2012. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 14 May 2012.

## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex(es) and appendix.

London, 16 May 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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 ulcerative colitis*

The waiver applies to:

- Children from birth to less than 2 years of age,
- for solution for injection in pre-filled syringe, solution for injection in pre-filled pen, 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).

## 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 in pre-filled syringe

Solution for injection in pre-filled pen

Concentrate for solution for infusion

#### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 1 | Study 1<br>Development of solution for injection for subcutaneous use in pre-filled single-dose syringe with age-appropriate total amount of active substance. |

| Area | Number of studies | Description |
|---|---|---|
| Non-clinical | 0 | Not applicable. |
| Clinical | 2 | Study 2<br><br>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.<br><br>Study 3<br><br>Double-blind, randomised-withdrawal, placebo-controlled, 3-arm multicentre study to assess the safety and efficacy of golimumab in patients from 2 to less than 18 years old with moderately to severely active ulcerative colitis. |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety and efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By September 2021 |
| Deferral for one or more 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 (RA)

   Authorised indication:

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 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 (see section 5.1) and to improve physical function.

3. 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.

| **EU Number** | **Invented name** | **Strength** | **Pharma-ceutical form** | **Route of administration** | **Pack-aging** | **Content (concent-ration)** | **Package size** |
|---|---|---|---|---|---|---|---|
| EU/1/09/546/001 | Simponi | 50 mg | Solution for injection in prefilled pen | Subcutaneous use | Pre-filled pen (glass) | 0.5 ml | 1 pre-filled pen |
| EU/1/09/546/002 | Simponi | 50 mg | Solution for injection in prefilled pen | Subcutaneous use | Pre-filled pen (glass) | 0.5 ml | 3 (3x1) pre-filled pens |
| EU/1/09/546/003 | Simponi | 50 mg | Solution for injection in prefilled syringe | Subcutaneous use | Pre-filled syringe (glass) | 0.5 ml | 1 pre-filled syringe |
| EU/1/09/546/004 | Simponi | 50 mg | Solution for injection in prefilled syringe | Subcutaneous use | Pre-filled syringe (glass) | 0.5 ml | 3 (3x1) pre-filled syringes |