EMA/469942/2010

European Medicines Agency decision

P/141/2010

of 30 July 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457), (EMEA-000380-PIP02-09) 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 application submitted by Novartis Europharm Limited on 16 October 2009 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 11 June 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457), powder for solution for injection or 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 recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457), powder for solution for injection or 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 recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457), powder for solution for injection or 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 is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.

Done at London, 30 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/315258/2010

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

EMEA-000380-PIP02-09

Scope of the application

Active substance(s):

Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457)

Condition(s):

Juvenile idiopathic arthritis

Rheumatoid arthritis

Ankylosing spondylarthritis

Pharmaceutical form(s):

Powder for solution for injection or infusion

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 16 October 2009 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 19 November 2009.

Supplementary information was provided by the applicant on 31 March 2009.

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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 Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations, 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(s) agree(s) 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, 11 June 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Juvenile idiopathic arthritis

Rheumatoid arthritis

Ankylosing spondylarthritis

2. Waiver

2.1. Condition

Juvenile idiopathic arthritis

The waiver applies to:

- Children from birth to less than 2 years
- for powder for solution for injection or infusion for subcutaneous use and 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.

2.2. Condition

Rheumatoid arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for powder for solution for injection or infusion for subcutaneous use and intravenous use
- on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations

2.3. Condition

Ankylosing spondylarthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for powder for solution for injection or infusion for subcutaneous use and intravenous use
- on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Juvenile idiopathic arthritis

3.1.1. Indication targeted by the PIP

Treatment of juvenile idiopathic arthritis (extended oligoarthritis, RF+ polyarthritis, RF- polyarthritis, systemic JIA without systemic manifestations and polyarticular course, enthesitis related arthritis, psoriatic arthritis)

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

From 2 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Solution for injection/infusion for intravenous use or subcutaneous use

3.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age appropriate formulation for intravenous use or subcutaneous use
Non-clinical	0	Not applicable.
Clinical	2	Study 2 Population pharmacokinetic modelling Study 3 Multicentre double-blind three arm two-dose randomised placebo controlled withdrawal study to evaluate efficacy and safety of AIN457 in children with juvenile idiopathic arthritis

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes