EMA/314974/2011

European Medicines Agency decision

P/115/2011

of 6 May 2011

on the acceptance of a modification of an agreed paediatric investigation plan for canakinumab, (EMEA-000060-PIP02-08-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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on the acceptance of a modification of an agreed paediatric investigation plan for canakinumab, (EMEA-000060-PIP02-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/131/2009 issued on 15 July 2009, the decision P/238/2009 issued on 1 December 2009,

Having regard to the application submitted by Novartis Europharm Limited on 6 December 2010 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 20 April 2011, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, 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 canakinumab, powder for solution for injection, subcutaneous 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB Horsham, United Kingdom.

Done at London, 6 May 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/299360/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan (after re-examination)

EMEA-000060-PIP02-08-M02

Scope of the application

Active substance(s):

Canakinumab

Condition(s):

Treatment of juvenile idiopathic arthritis

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 6 December 2010 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/131/2009 issued on 15 July 2009 and the decision P/238/2009 issued on 1 December 2009.

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

An Opinion was adopted by the Paediatric Committee on 18 February 2011 for the above mentioned product. Novartis Europharm Limited received the Paediatric Committee Opinion on 24 February 2011.

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On 18 March 2011 Novartis Europharm Limited submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 19 March 2011.

A meeting with the Paediatric Committee took place on 20 April 2011.

Scope of the modification

Some measures and timelines of the original Opinion have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and to agree to the changes regarding the measures and the timelines of the paediatric investigation plan and the timelines of 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 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, 20 April 2011

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 juvenile idiopathic arthritis

The waiver applies to:

- Preterm and term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months),
- for the powder for solution for injection for 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 subsets and
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of juvenile idiopathic arthritis

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis.

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

From 24 months to less than 18 years.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection for subcutaneous use.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	4	**Study 1) CACZ885A2203** A multi-centre, open label, repeated dose range finding study to evaluate the safety, tolerability, immunogenicity and pharmacokinetics of canakinumab given subcutaneously in paediatric subjects with active systemic juvenile idiopathic arthritis. **Study 2)** A randomized, double-blind, placebo controlled, single-dose study to assess the efficacy of canakinumab in patients from 2 years to less than 20 years of age with Systemic Juvenile Idiopathic Arthritis (sJIA) and active systemic manifestations. **Study 3)**

Area	Number of studies	Description
		A randomized, double-blind, placebo controlled, withdrawal study of flare prevention of canakinumab in patients from 2 years to less than 20 years of age with Systemic Juvenile Idiopathic Arthritis (sJIA) and active systemic manifestations. **Study 4)** An open-label extension study canakinumab in patients with Systemic Juvenile Idiopathic Arthritis (sJIA) and active systemic manifestations.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2013
Deferral for one or more studies contained in the paediatric investigation plan:	Yes