EMA/331976/2013

European Medicines Agency decision

P/0141/2013

of 3 July 2013

on the acceptance of a modification of an agreed paediatric investigation plan for canakinumab (Ilaris) (EMEA-000060-PIP02-08-M06) 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 (Ilaris) (EMEA-000060-PIP02-08-M06) 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, the decision P/115/2011 issued on 6 May 2011, the decision P/218/2011 issued on 26 September 2011, the decision P/296/2011 issued on 20 December 2011, and the decision P/0108/2012 issued on 8 June 2012,

Having regard to the application submitted by Novartis Europharm Limited on 22 February 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 17 May 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 canakinumab (Ilaris), powder for solution for injection, powder and solvent for solution for injection, solution for injection in pre-filled syringe, 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, 3 July 2013

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

EMA/PDCO/136851/2013 Corr

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

EMEA-000060-PIP02-08-M06

Scope of the application

Active substance(s):

Canakinumab

Invented name:

Ilaris

Condition(s):

Treatment of juvenile idiopathic arthritis

Treatment of cryopyrin associated periodic syndromes (CAPS) including:

- Familial cold autoinflammatory syndrome (FCAS) / familial cold urticaria (FCU)
- Muckle-Wells syndrome (MWS)

Neonatal-onset multisystem inflammatory disease (NOMID) / chronic infantile neurological, cutaneous, articular syndrome (CINCA)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Powder and solvent for solution for injection

Solution for injection in pre-filled syringe

Route(s) of administration:

Subcutaneous use

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Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

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 22 February 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/131/2009 issued on 15 July 2009, the decision P/238/2009 issued on 1 December 2009, the decision P/115/2011 issued on 6 May 2011, the decision P/218/2011 issued on 26 September 2011, the decision P/296/2011 issued on 20 December 2011, and the decision P/0108/2012 issued on 8 June 2012.

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

The procedure started on 20 March 2013.

Scope of the modification

Some measures of the original 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 in the scope set out in the Annex I of this opinion.

   The Icelandic and the Norwegian Paediatric Committee members agree 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, 17 May 2013

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, powder and solvent for solution for injection, and 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.

1.2. Condition: Treatment of Cryopyrin Associated Periodic Syndromes (CAPS)

including:

- Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU);
- Muckle-Wells Syndrome (MWS);
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).

The waiver applies to:

- Newborn infants (from birth to less than 28 days);
- for powder for solution for injection, powder and solvent for solution for injection, and solution for injection, for subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

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;

Powder and solvent for solution for injection;

Solution for injection in pre-filled syringe.

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) CACZ885G2305 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) CACZ885G2301 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) CACZ885G2301E1 An open-label extension study canakinumab in patients with Systemic Juvenile Idiopathic Arthritis (sJIA) and active systemic manifestations.

2.2. Condition: Treatment of Cryopyrin Associated Periodic Syndromes (CAPS)

2.2.1. Indication(s) targeted by the PIP

Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in paediatric patients of infant age and older, including:

- Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU);
- Muckle-Wells Syndrome (MWS);
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).

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

From one month to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for solution for injection;

Powder and solvent for solution for injection;

Solution for injection in pre-filled syringe.

2.2.4. Studies

For measures in this condition, reference is made to PIP no. EMEA-000060-PIP01-07 that has been agreed pursuant to EMA decision no. P/27/2008 dated 23 May 2008 including any subsequent modifications.

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 June 2015
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 Cryopyrin-Associated Periodic Syndromes (CAPS)

   Authorised indication(s):

   Ilaris is indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS) in adults, adolescents and children aged two years and older with body weight above 15 kg, including:

   - Muckle-Wells syndrome (MWS);
   - neonatal-onset multisystem inflammatory disease (NOMID) / chronic infantile neurological, cutaneous, articular syndrome (CINCA);
   - severe forms of familial cold auto-inflammatory syndrome (FCAS) / familial cold urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.

Authorised pharmaceutical form(s):

Powder for solution for injection, Powder and solvent for solution for injection,

Authorised route(s) of administration:

Subcutaneous use