EMA/627039/2015

European Medicines Agency decision

P/0239/2015

of 30 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for canakinumab, (Ilaris) (EMEA-000060-PIP05-14-M01) 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/0058/2015 issued on 1 April 2015,

Having regard to the application submitted by Novartis Europharm Limited on 17 June 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 September 2015, 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), solution for injection, powder for solution for injection, powder and solvent 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 agreed paediatric investigation plan covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/27/2008, EMEA-000060-PIP01-07 issued on 23 May 2008, including subsequent modifications thereof; P/131/2009, EMEA-000060-PIP02-08 issued on 15 July 2009, including subsequent modifications thereof; P/0057/2015, EMEA-000060-PIP04-14 issued on 01 April 2015 including subsequent modifications thereof.

Article 3

This decision is addressed to Novartis Europharm Limited, Frimley Business Park, GU16 7SR – Camberley, United Kingdom,

Done at London, 30 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/468374/2015 corr
London, 11 September 2015

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

EMEA-000060-PIP05-14-M01

Scope of the application

Active substance(s):

Canakinumab

Invented name:

Ilaris

Condition(s):

Treatment of tumour necrosis factor receptor associated periodic syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Powder for solution for injection

Powder and solvent for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

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, Novartis Europharm Limited submitted to the European Medicines Agency on 17 June 2015 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0058/2015 issued on 1 April 2015.

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

The procedure started on 14 July 2015.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to include other conditions.

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 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.

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 tumour necrosis factor receptor associated periodic syndrome

The waiver applies to:

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

2. Paediatric investigation plan

2.1. Condition:

Treatment of tumour necrosis factor receptor associated periodic syndrome

2.1.1. Indication(s) targeted by the PIP

Treatment of tumour necrosis factor receptor associated periodic syndrome in paediatric patients from 28 days to less than 18 years of age

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

From 28 days to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of 1:1 dilution procedure with commercially available diluents (same study as for conditions “treatment of familial Mediterranean fever” and “treatment of hyperimmunoglobulin D syndrome”).
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Randomized, multicentre, double-blind, placebo controlled study to evaluate efficacy and safety of canakinumab compared to placebo in children from 2 years to less than 18 years of age (and adults), and to collect efficacy and safety data in children from 28 days to less than 2 years of age with Hereditary Periodic Fevers (familial Mediterranean fever, hyperimmunoglobulin D syndrome and TNF receptor associated periodic syndrome) (CACZ885N2301) (same study as for conditions “treatment of familial Mediterranean fever” and “treatment of hyperimmunoglobulin D syndrome”)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. 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):

- Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above, including:
  - Muckle-Wells Syndrome (MWS),
  - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA),
  - Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.

2. Treatment of juvenile idiopathic arthritis

Authorised indication(s):

- Ilaris is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.

3. Treatment of primary gout (excluding Lesh-Nyhan syndrome and other secondary forms of gout)

Authorised indication(s):

- Ilaris is indicated for the symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

Authorised pharmaceutical form(s):

Powder for solution for injection

Powder and solvent for solution for injection

Authorised route(s) of administration:

Subcutaneous use.