EMA/184118/2012

European Medicines Agency decision

P/0066/2012

of 28 March 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for anakinra (Kineret), (EMEA-001212-PIP01-11) 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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/0066/2012

of 28 March 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for anakinra (Kineret), (EMEA-001212-PIP01-11) 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 application submitted by Swedish Orphan Biovitrum AB (publ) on 10 October 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 February 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 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 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 anakinra (Kineret), solution for injection, subcutaneous 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 waiver for anakinra (Kineret), solution for injection, subcutaneous 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

This decision is addressed to Swedish Orphan Biovitrum AB (publ), Tomtebodavägen 23A, SE 112 76 – Stockholm, Sweden.

Done at London, 28 March 2012

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

EMA/PDCO/76138/2012

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

EMEA-001212-PIP01-11

Scope of the application

Active substance(s):

Anakinra

Invented name:

Kineret

Condition(s):

Treatment of cryopyrin-associated periodic syndromes (CAPS)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Swedish Orphan Biovitrum AB (publ)

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Swedish Orphan Biovitrum AB (publ) submitted for agreement to the European Medicines Agency on 10 October 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 14 December 2011.

Supplementary information was provided by the applicant on 27 January 2012. The applicant proposed modifications to the paediatric investigation plan.

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 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 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, 10 February 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 cryopyrin-associated periodic syndromes (CAPS)

The waiver applies to:

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

1.2. Condition:Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

The waiver applies to:

- Children from birth to less than 1 year of age;
- for solution for injection, 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 subset(s).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of cryopyrin-associated periodic syndromes (CAPS)

2.1.1. Indication(s) targeted by the PIP

Treatment of cryopyrin-associated periodic syndromes (CAPS), which includes familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS) and neonatal-onset multisystemic inflammatory disease/chronic infantile neurological cutaneous articular syndrome (NOMID/CINCA).

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection.

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	1	Study 1 Development of pre-filled syringe enabling accurate dosing for children.
Non-clinical	0	Not applicable.
Clinical	3	Study 2 Prospective single centre open-label study to evaluate safety and clinical response in patients with neonatal onset multisystem inflammatory disease (NOMID/CINCA syndrome). Study 3 Randomised blinded placebo controlled withdrawal to evaluate the efficacy, safety, and pharmacokinetics of anakinra in polyarticular course juvenile rheumatoid arthritis. Study 4 Analysis of available published data on efficacy and safety of anakinra in patients with CAPS.

2.2. Condition: Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis)

2.2.1. Indication(s) targeted by the PIP

Treatment of systemic JIA.

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

From 1 year to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection.

2.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of pre-filled syringe enabling accurate dosing for children.
Non-clinical	0	Not applicable.
Clinical	3	Study 3 Randomised blinded placebo controlled withdrawal to evaluate the efficacy, safety, and pharmacokinetics of anakinra in polyarticular course juvenile rheumatoid arthritis. Study 5 A multicentre randomised double-blind placebo-controlled trial to evaluate safety and efficacy of anakinra in patients with systemic-onset juvenile idiopathic arthritis. Study 6 Analysis of available published data on efficacy and safety of anakinra in patients with systemic JIA.

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 December 2013.
Deferral for one or more studies contained in the paediatric investigation plan:	No.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of rheumatoid arthritis

   Authorised indications:

   Kineret is indicated for the treatment of the signs and symptoms of rheumatoid arthritis in combination with methotrexate, in adults with an inadequate response to methotrexate alone.

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/02/203/001	Kineret	100 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.67 ml (150 mg/ml)	1 pre-filled syringe
EU/1/02/203/002	Kineret	100 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.67 ml (150 mg/ml)	7 pre-filled syringes
EU/1/02/203/003	Kineret	100 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.67 ml (150 mg/ml)	28 pre-filled syringes
EU/1/02/203/004	Kineret	100 mg	Solution for injection	Subcutaneous use	vial (glass)	0.67 ml (150 mg/ml)	1 vial