European Medicines Agency

Doc. Ref. EMEA/760824/2009
P/238/2009

EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for canakinumab (EMEA-000060-PIP02-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for canakinumab (EMEA-000060-PIP02-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/131/2009 of the European Medicines Agency on 15 July 2009,

Having regard to the application submitted by Novartis Europharm Limited on 7 August 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 October 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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, 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/131/2009, as far as the agreed changes to the PIP for canakinumab are concerned, is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.

Done at London, 1 December 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/612753/2009
EMEA-000060-PIP02-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Canakinumab

Condition(s):
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 EMEA on 7 August 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the EMEA decision P/131/2009 of 15 July 2009. The application for modification proposed changes.

The procedure started on 20 August 2009.

Scope of the modification

The modification addressed criteria for the design and timelines of the clinical studies.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Opinion

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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix(ces).

London, 16 October 2009

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

A. CONDITION(S)

Juvenile Idiopathic Arthritis

B. WAIVER

- **Condition**

Systemic-onset 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Juvenile Idiopathic Arthritis

- **Proposed PIP indication**

Treatment of Juvenile Idiopathic Arthritis

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 24 months to less than 18 years.

- **Formulation(s)**

Powder for solution for injection for subcutaneous use

- **Studies**

Area	Number of studies	Description
Quality	1	A parenteral formulation of appropriate concentration to allow accurate dosing of paediatric patients aged 2-18 years without unnecessary wastage.
Non-clinical		Not applicable.
Clinical	4	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. 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. 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. An open-label extension study canakinumab in patients with Systemic Juvenile Idiopathic Arthritis (sJIA) and active systemic manifestations.

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 June 2013**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**