EMA/267488/2010

European Medicines Agency decision

P/71/2010

of 5 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for tocilizumab (RoActemra) (EMEA-000309-PIP01-08-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 tocilizumab (RoActemra) (EMEA-000309-PIP01-08-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/57/2009 issued on 25 March 2009 and the decision P/129/2009 issued on 14 July 2009,

Having regard to the application submitted by Roche Registration Limited on 1 February 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 19 March 2010, 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 tocilizumab (RoActemra), concentrate for solution for infusion, intravenous 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 Roche Registration Limited, 6 Falcon Way, Shire Park, AL7 1TW Welwyn Garden City, United Kingdom.

Done at London, 5 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/150654/2010

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

EMEA-000309-PIP01-08-M02

Scope of the application

Active substance(s):

Tocilizumab

Invented name:

RoActemra

Condition(s):

Autoimmune arthritis

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Roche Registration 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, Roche Registration Limited submitted to the European Medicines Agency on 1 February 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/129/2009 of 14 July 2009. The application for modification proposed changes.

The procedure started on 18 February 2010.

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Scope of the modification

Changes in the long term follow-up measures.

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 the changes proposed by the applicant regarding the measures of the paediatric investigation plan

   The Norwegian Paediatric Committee member 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 annex(es) and appendix.

London, 19 March 2010

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

1. Condition(s)

Autoimmune arthritis

2. Waiver

2.1. Condition

Juvenile idiopathic arthritis

The waiver applies to:

- Preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), for concentrate for solution for infusion for intravenous use,

on the grounds that measures would not be justified by expected therapeutic benefit as clinical trials are not feasible.

2.2. Condition

Rheumatoid arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age for the concentrate for solution for infusion for intravenous 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).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Autoimmune arthritis

3.1.1. Indication targeted by the PIP

Treatment of moderate to severe systemic-onset juvenile idiopathic arthritis (sJIA) in patients aged from 2 years to less than 18 years with active sJIA for at least 6 months, who have had an inadequate response to NSAIDs and / or systemic corticosteroids.

Treatment of active polyarticular-course juvenile idiopathic arthritis (rheumatoid factor-positive polyarthritis, rheumatoid factor-negative polyarthritis and extended oligoarticular arthritis) in patients aged from 2 years to less than 18 years with active disease who have had an inadequate response or are intolerant to methotrexate.

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

From 2 years to less than 18 years.

3.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion, intravenous use, 20 mg/ml

3.1.4. Studies

Area	Number of studies	Description
Quality	**0**	Not applicable
Non-clinical	**0**	Not applicable
Clinical	**2**	Randomised, double-blind, placebo-controlled, parallel-group, 2-arm 12-week study to evaluate the efficacy and safety of tocilizumab in patients aged from 2 years to less than 18 years with active systemic juvenile idiopathic arthritis with 92-week single-arm open-label extension Open-label, multi-centre withdrawal study to evaluate the efficacy and safety of tocilizumab in patients aged from 2 years to less than 18 years with active polyarticular-course juvenile idiopathic arthritis, with open-label extension

4. 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 September 2012
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/08/492/001	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	4 ml	1 vial
EU/1/08/492/002	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	4 ml	4 vials
EU/1/08/492/003	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	10 ml	1 vial
EU/1/08/492/004	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	10 ml	4 vials
EU/1/08/492/005	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	20 ml	1 vial
EU/1/08/492/006	RoActemra	20 mg/ml	Concentrate for solution for infusion	Intravenous use	vial (glass)	20 ml	4 vials