EMA/38628/2017

European Medicines Agency decision

P/0010/2017

of 31 January 2017

on the acceptance of a modification of an agreed paediatric investigation plan for ranibizumab (Lucentis), (EMEA-000527-PIP04-13-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 decision P/0186/2014 issued on 6 August 2014,

Having regard to the application submitted by Novartis Europharm Limited on 22 September 2016 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 16 December 2016, 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 ranibizumab (Lucentis), solution for injection, intravitreal 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, Frimley Business Park, GU16 7SR – Camberley, United Kingdom.

EMA/PDCO/654005/2016
London, 16 December 2016

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

EMEA-000527-PIP04-13-M01

Scope of the application

Active substance(s):

Ranibizumab

Invented name:

Lucentis

Condition(s):

Treatment of retinopathy of prematurity

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravitreal 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 22 September 2016 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0186/2014 issued on 6 August 2014.

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

The procedure started on 18 October 2016.

Scope of the modification

Some measures of the 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 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 retinopathy of prematurity

The waiver applies to:

- term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), children (from 2 to less than 12 years) and adolescents (from 12 to less than 18 years);
- solution for injection, intravitreal 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 retinopathy of prematurity

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with retinopathy of prematurity

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

Preterm infants

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 a low volume syringe to ensure dose accuracy
Non-clinical studies		Not applicable.
Clinical studies	1	**Study 2** Open-label, randomized, parallel-group superiority study to evaluate the efficacy and safety of ranibizumab compared to laser therapy for the treatment of retinopathy of prematurity (ROP).

Extrapolation, modelling and simulation studies		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 December 2018
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 age-related macular degeneration

Authorised indication(s):

Lucentis is indicated in adults for:

- the treatment of neovascular (wet) age-related macular degeneration (AMD).

2. Treatment of macular oedema

Authorised indication(s):

Lucentis is indicated in adults for:

- the treatment of visual impairment due to diabetic macular oedema (DME).
- the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

3. Treatment of choroidal neovascularisation

Authorised indication(s):

Lucentis is indicated in adults for:

- the treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM).

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intravitreal use