EMA/182951/2019

European Medicines Agency decision

P/0115/2019

of 4 April 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for aflibercept (Eylea), (EMEA-000236-PIP05-18) 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 application submitted by Bayer AG on 13 July 2018 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 1 March 2019, in accordance with Article 17 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 aflibercept (Eylea), solution for injection, intravitreal 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 aflibercept (Eylea), solution for injection, intravitreal 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 Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 – Leverkusen, Germany.

EMA/PDCO/838124/2018
London, 1 March 2019

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

EMEA-000236-PIP05-18

Scope of the application

Active substance(s):

Aflibercept

Invented name:

Eylea

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:

Bayer AG

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted for agreement to the European Medicines Agency on 13 July 2018 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 21 August 2018.

Supplementary information was provided by the applicant on 23 November 2018. 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 17(1) 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   The Norwegian Paediatric Committee member agrees 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 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 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** Develop or identify an application device to ensure accuracy for administration of 10 microliters
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2 (20090)** Open-label, randomised, controlled study to assess the efficacy, safety, and tolerability of intravitreal (IVT) aflibercept in patients with retinopathy of prematurity (ROP)

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	1	**Study 3** Historical/published evidence synthesis study
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 July 2022
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):

   Eylea is indicated for adults for the treatment of

   - neovascular (wet) age-related macular degeneration (AMD)

2. Treatment of central retinal vein occlusion

   Authorised indication(s):

   Eylea is indicated for adults for the treatment of

   - visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)

3. Treatment of diabetic macular oedema

   Authorised indication(s):

   Eylea is indicated for adults for the treatment of

   - visual impairment due to diabetic macular oedema (DME)

4. Treatment of choroidal neovascularisation

   Authorised indication(s):

   Eylea is indicated for adults for the treatment of

   - visual impairment due to myopic choroidal neovascularisation

Authorised pharmaceutical form(s):

Solution for injection, solution for injection in pre-filled syringe

Authorised route(s) of administration:

Intravitreal use