EMA/102305/2018

European Medicines Agency decision

P/0060/2018

of 16 March 2018

on the acceptance of a modification of an agreed paediatric investigation plan for octocog alfa (Iblias, Kovaltry) (EMEA-001064-PIP01-10-M03) 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 P/126/2011 issued on 7 June 2011, the decision P/0259/2013 issued on 29 October 2013 and the decision P/0107/2014 issued on 5 May 2014,

Having regard to the application submitted by Bayer AG on 2 November 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 January 2018, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 octocog alfa (Iblias, Kovaltry), powder and solvent for solution for injection, intravenous use, including changes to the deferral, 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 Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 – Leverkusen, Germany.

EMA/PDCO/760586/2017
London, 26 January 2018

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

EMEA-001064-PIP01-10-M03

Scope of the application

Active substance(s):

Octocog alfa

Invented name:

Iblias

Kovaltry

Condition(s):

Treatment of hereditary factor VIII deficiency

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bayer AG

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted to the European Medicines Agency on 2 November 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/126/2011 issued on 7 June 2011, the decision P/0259/2013 issued on 29 October 2013 and the decision P/0107/2014 issued on 5 May 2014.

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

The procedure started on 28 November 2017.

Scope of the modification

Some measures and timelines 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 and to the deferral 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 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

Not applicable

2. Paediatric Investigation Plan

2.1. Condition: treatment of hereditary factor VIII deficiency

2.1.1. Indication(s) targeted by the PIP

Treatment and prophylaxis of bleeding in patients with haemophilia A

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	5	**Study 1:** Open-label, multicentre, cross-over, single dose trial to evaluate pharmacokinetics of new Octocog alfa (BAY 81-8973) as compared to already authorised Octocog alfa (KOGENATE Bayer), in previously treated adult and adolescent patients at least 12 years of age, with hereditary factor VIII deficiency **Study 2:** Open-label, multicentre, uncontrolled, cross-over comparing two different methods (assays) for measuring the amount of study drug, multiple dose trial to evaluate safety and efficacy of new Octocog alfa (BAY 81-8973), in previously treated adult and adolescent patients at least 12 years of age, with hereditary factor VIII deficiency **Study 3:** Open-label, multicentre, uncontrolled, multiple dose trial to evaluate safety, efficacy and pharmacokinetics of new Octocog alfa (BAY 81-8973) for prophylaxis and treatment of bleeding, in previously treated patients less than 12 years of age, with hereditary factor VIII deficiency

		Study 4: Open-label, multicentre, uncontrolled, multiple dose trial to evaluate efficacy and safety of new Octocog alfa (BAY 81-8973) for prophylaxis and treatment of bleeding in previously untreated children with hereditary factor VIII deficiency. **Study 5:** Open-label, multicentre, uncontrolled, multiple dose trial to monitor the safety of new Octocog alfa (BAY 81-8973), including immunogenicity, in patients with hereditary factor VIII deficiency who participated in 13400 Part A (Study 3) or 13400 Part B (Study 4).

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of hereditary factor VIII deficiency

Authorised indication(s):

- Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). **Iblias** can be used for all age groups.
- Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). **Kovaltry** can be used for all age groups.

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection

Authorised route(s) of administration:

Intravenous use