EMA/466902/2017

European Medicines Agency decision

P/0207/2017

of 9 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689) (EMEA-001886-PIP01-15-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 P/0342/2016 issued on 2 December 2016,

Having regard to the application submitted by CSL Behring GmbH on 3 April 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 June 2017, 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 recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689), powder and solvent for solution for injection, 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 CSL Behring GmbH, Emil-von-Behring Str. 76, 35041 – Marburg, Germany.

EMA/PDCO/225088/2017
London, 23 June 2017

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

EMEA-001886-PIP01-15-M01

Scope of the application

Active substance(s):

Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689)

Condition(s):

Treatment of Haemophilia A

Treatment of Haemophilia B

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

CSL Behring GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, CSL Behring GmbH submitted to the European Medicines Agency on 3 April 2017 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0342/2016 issued on 2 December 2016.

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

The procedure started on 25 April 2017.

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 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 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 Haemophilia A

2.1.1. Indication(s) targeted by the PIP

Treatment of Haemophilia A with inhibitors

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. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1** Multicentre, open-label, multiple-dose, dose escalation study to evaluate pharmacokinetics, efficacy, and safety of rVIIa-FP (CSL689) in children and adults with haemophilia A or B and inhibitors. **Study 2** Multicentre open-label multi-dose study to investigate PK, efficacy and safety of prophylactic treatment of CSL689 in children and adults with haemophilia A or B with inhibitors.
Extrapolation, modelling and simulation studies	2	**Study 3** Dose finding Population Pharmacokinetic (PopPK) model. **Study 4** Dose selection study using extrapolation

Area	Number of measures	Description
Other studies	0	Not applicable
Other measures	0	Not applicable

2.2. Condition

Treatment of Haemophilia B

2.2.1. Indication(s) targeted by the PIP

Treatment of Haemophilia B with inhibitors

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1** Same as for condition “Treatment of Haemophilia A” **Study 2** Same as for condition “Treatment of Haemophilia A”
Extrapolation, modelling and simulation studies	2	**Study 3** Same as for condition “Treatment of Haemophilia A” **Study 4** Same as for condition “Treatment of Haemophilia A”
Other studies	0	Not applicable
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 June 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No