EMA/429548/2023

European Medicines Agency decision

P/0421/2023

of 27 October 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for ciraparantag (EMEA-003321-PIP01-22) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by NORGINE BV on 9 September 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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 deferral.

(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 deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for ciraparantag, solution for injection, intravenous 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 deferral for ciraparantag, solution for injection, intravenous 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 NORGINE BV, 150 Antonio Vivaldistraat, 1083 HP – Amsterdam, The Netherlands.

EMA/PDCO/259862/2023
Amsterdam, 8 September 2023

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

EMEA-003321-PIP01-22

Scope of the application

Active substance(s):

Ciraparantag

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of factor Xa inhibitor associated haemorrhage

Treatment of factor Xa inhibitor associated haemorrhage

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

NORGINE BV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, NORGINE BV submitted for agreement to the European Medicines Agency on 9 September 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 17 October 2022.

Supplementary information was provided by the applicant on 19 May 2023. 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 deferral in accordance with Article 21 of said Regulation.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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:

Prevention of factor Xa inhibitor associated haemorrhage

2.1.1. Indication(s) targeted by the PIP

For patients treated with a direct FXa inhibitor (apixaban or edoxaban or rivaroxaban) when rapid reversal of anticoagulation is needed due to either major or life-threatening bleeding, or prior to urgent or emergency surgery or procedures

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)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of appropriately sized vials to cover all the paediatric population.
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Double-blind, randomised, single-dose, placebo-controlled study to evaluate the pharmacokinetics, pharmacodynamics and safety of ciraparantag in children from birth to less than 18 years of age administered with rivaroxaban for treatment of venous thromboembolism (VTE). **Study 3** Double-blind, randomised, single-dose, placebo-controlled study to evaluate the pharmacokinetics, pharmacodynamics and safety of ciraparantag in children from birth to less than 18 years of age administered with apixaban for treatment of venous thromboembolism (VTE).

	Study 4 Double-blind, randomised, single-dose, placebo-controlled study to evaluate the pharmacokinetics, pharmacodynamic and safety of ciraparantag in children from birth to less than 18 years of age administered with edoxaban for treatment of venous thromboembolism (VTE).
Modelling and simulation studies	**Study 5** Modelling and simulation study to evaluate the use of ciraparantag in children from birth to less than 18 years of age administered with rivaroxaban for treatment of venous thromboembolism (VTE). **Study 6** Modelling and simulation study to evaluate the use of ciraparantag in children from birth to less than 18 years of age administered with apixaban for treatment of venous thromboembolism (VTE). **Study 7** Modelling and simulation study to evaluate the use of ciraparantag in children from birth to less than 18 years of age administered with edoxaban for treatment of venous thromboembolism (VTE).
Other studies	Not applicable
Extrapolation plan	Not applicable

2.2. Condition:

Treatment of factor Xa inhibitor associated haemorrhage

2.2.1. Indication(s) targeted by the PIP

For patients treated with a direct Factor Xa inhibitor (apixaban or edoxaban or rivaroxaban) when rapid reversal of anticoagulation is needed due to either major or life-threatening bleeding, or prior to urgent or emergency surgery or procedures

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)

Solution for injection

2.2.4. Measures

The same as for condition ‘prevention of factor Xa inhibitor associated haemorrhage ‘

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2035
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.