EMA/215040/2019

# European Medicines Agency decision

P/0151/2019

of 17 April 2019

on the acceptance of a modification of an agreed paediatric investigation plan for idarucizumab (Praxbind), (EMEA-001438-PIP01-13-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 P/0069/2014 issued on 17 March 2014,

Having regard to the application submitted by Boehringer Ingelheim international GmbH on 26 November 2018 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 1 March 2019, 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 Idarucizumab (Praxbind), solution for injection/infusion, 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 Boehringer Ingelheim international GmbH, Binger Strasse 173, 55216 – Ingelheim, Germany.

EMA/PDCO/854634/2018
London, 1 March 2019

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

EMEA-001438-PIP01-13-M01

## Scope of the application

**Active substance(s):**

Idarucizumab

**Invented name:**

Praxbind

**Condition(s):**

Prevention of dabigatran associated haemorrhage

Treatment of dabigatran associated haemorrhage

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Solution for injection/infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Boehringer Ingelheim international GmbH

**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, Boehringer Ingelheim international GmbH submitted to the European Medicines Agency on 26 November 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0069/2014 issued on 17 March 2014.

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

The procedure started on 3 January 2019.

## Scope of the modification

Some 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 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*

Prevention of dabigatran associated haemorrhage

### 2.1.1. Indication(s) targeted by the PIP

Prevention of haemorrhage in patients who require emergency surgery/procedures when rapid reversal of the anticoagulant effects of dabigatran is needed

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

Children from birth to less than 18 years

### 2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

### 2.1.4. Measures

| **Area** | **Number of studies** | **Description** |
|---|---|---|
| Quality-related measures | 0 | Not applicable. |
| Non-clinical studies | 0 | Not applicable. |
| Clinical studies | 2 | **Study 1**<br>Single dose, open label study of administration of idarucizumab as rescue medication to patients in paediatric dabigatran trials to assess safety in children from birth to less than 18 years. |
| Extrapolation, modelling and simulation studies | 0 | Not applicable |
| Other studies | 0 | Not applicable |
| Other measures | 1 | **Study 2**<br>Establishment of a registry of all paediatric patients treated with idarucizumab. |

## *2.2. Condition*

Treatment of dabigatran associated haemorrhage

### 2.2.1. Indication(s) targeted by the PIP

Treatment of uncontrolled or life-threatening bleeding which requires urgent intervention in patients treated with dabigatran.

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

Children from birth to less than 18 years

### 2.2.3. Pharmaceutical form(s)

Solution for injection/infusion.

### 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**<br>Single dose, open label study of administration of idarucizumab as rescue medication to patients in paediatric dabigatran trials to assess safety in children from birth to less than 18 years. |
| Extrapolation, modelling and simulation studies | 0 | Not applicable |
| Other studies | 0 | Not applicable |
| Other measures | 1 | **Study 2**<br>Establishment of a registry of all paediatric patients treated with idarucizumab. |

# 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 February 2020 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of dabigatran associated haemorrhage

Authorised indication(s):

- Praxbind is a specific reversal agent for dabigatran and is indicated in patients treated with Pradaxa (dabigatran etexilate) when rapid reversal of the anticoagulant effects of dabigatran is required:
  - For emergency surgery/ urgent procedures
  - In life-threatening or uncontrolled bleeding

## Authorised pharmaceutical form(s):

Solution for injection/infusion

## Authorised route(s) of administration:

Intravenous use