EMA/469423/2023

European Medicines Agency decision

P/0415/2023

of 25 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for angiotensin II (LJPC-501), (Giapreza), (EMEA-001912-PIP02-16-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0271/2017 issued on 4 October 2017, the decision P/0130/2018 issued on 6 April 2018 and the decision P/0159/2019 issued on 15 April 2019.

Having regard to the application submitted by Paion Deutschland GmbH on 3 July 2023 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 8 September 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for angiotensin II (LJPC-501), (Giapreza), concentrate for solution for 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 Paion Deutschland GmbH, Heussstraße 25, 52078 – Aachen, Germany.

EMA/PDCO/315840/2023
Amsterdam, 8 September 2023

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

EMEA-001912-PIP02-16-M03

Scope of the application

Active substance(s):

Angiotensin II (LJPC-501)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypotension associated with distributive or vasodilatory shock

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Paion Deutschland GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Paion Deutschland GmbH submitted to the European Medicines Agency on 3 July 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0271/2017 issued on 4 October 2017, the decision P/0130/2018 issued on 6 April 2018 and the decision P/0159/2019 issued on 15 April 2019.

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

The procedure started on 14 August 2023.

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:

Treatment of hypotension associated with distributive or vasodilatory shock

2.1.1. Indication(s) targeted by the PIP

Treatment of hypotension associated with distributive or vasodilatory shock

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)

Concentrate for solution for infusion

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	**Study 1** Definitive juvenile toxicity study in newborn lamb
Clinical studies	**Study 2 - LJ501-CRH04** Double-blind, randomised placebo controlled trial to evaluate efficacy and safety of LJPC-501 in paediatric patients from 2 to less than 18 years of age with distributive shock who remain hypotensive despite fluid therapy and vasopressor therapy. (LJ501-CRH04) **Study 3 - LJ501-CRH05** Open-label, randomised, active controlled trial to evaluate efficacy and safety of LJPC-501 in paediatric patients from birth to less than 2 years of age with distributive shock who remain hypotensive despite fluid therapy and vasopressor therapy. (LJ501-CRH05)
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

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 2026
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:

Condition(s) and authorised indication(s)

1. Treatment of hypotension associated with distributive or vasodilatory shock

Authorised indication(s):

- Treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies
  - Invented name(s): Giapreza
  - Authorised pharmaceutical form(s): concentrate for solution for infusion
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure