EMA/666205/2016

European Medicines Agency decision

P/0292/2016

of 4 November 2016

on the acceptance of a modification of an agreed paediatric investigation plan for serelaxin (EMEA-001168-PIP01-11-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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on the acceptance of a modification of an agreed paediatric investigation plan for serelaxin (EMEA-001168-PIP01-11-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0139/2012 issued on 20 July 2012, the decision P/0288/2012 issued on 26 November 2012 and the decision P/0333/2014 issued on 22 December 2014,

Having regard to the application submitted by Novartis Europharm Limited on 27 June 2016 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 16 September 2016, 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 serelaxin, solution for infusion, 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 Novartis Europharm Limited, 210 Frimley Business Park, GU16 7SR - Frimley, United Kingdom.

EMA/PDCO/449068/2016
London, 16 September 2016

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

EMEA-001168-PIP01-11-M03

Scope of the application

Active substance(s):

Serelaxin

Condition(s):

Treatment of acute heart failure

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 27 June 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0139/2012 issued on 20 July 2012, the decision P/0288/2012 issued on 26 November 2012 and the decision P/0333/2014 issued on 22 December 2014.

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

The procedure started on 19 July 2016.

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 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 acute heart failure

2.1.1. Indication(s) targeted by the PIP

Treatment of acute heart failure following surgical repair of a congenital heart defect

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 infusion

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate formulation for intravenous use.
Non-clinical studies	2	**Study 2** Repeat dose, 4 week toxicology study in cynomolgus monkeys. **Study 3** Investigation of relaxin receptors expression in foetal, juvenile and adult tissues. *Study 4* *Deleted during procedure EMEA-001168-PIP01-11-M01*
Clinical studies	2	**Study 5** Open-label, dose escalation trial to evaluate safety, tolerability and pharmacokinetics/pharmacodynamics of serelaxin as add on to standard of care therapy in children from birth to less than 18 years old with acute heart failure (AHF).

		Study 6 Double-blind, randomised, placebo-controlled trial to evaluate efficacy, safety and tolerability of serelaxin as add on to standard of care therapy in children from birth to less than 18 years old with acute heart failure (AHF) following surgical repair of a congenital heart defect with a 6-month follow-up extension to evaluate safety.
Extrapolation, modelling and simulation studies	0	Not applicable.
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 July 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes