EMA/616446/2021

European Medicines Agency decision

P/0493/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for naloxegol (Moventig), (EMEA-001146-PIP01-11-M07) 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/0183/2012 issued on 21 August 2012, the decision P/0108/2014 issued on 5 May 2014, the decision P/0158/2016 issued on 15 June 2016, the decision P/0292/2017 issued on 4 October 2017, the decision P/0056/2019 issued on 11 February 2019, the decision P/0381/2019 issued on 4 December 2019 and the decision P/0513/2020 issued on 22 December 2020,

Having regard to the application submitted by Kyowa Kirin Pharmaceutical Development Limited on 12 July 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, 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 naloxegol (Moventig), tablet, age-appropriate oral liquid formulation, oral 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 Kyowa Kirin Pharmaceutical Development Limited, Galabank Business Park, TD1 1QH – Galashiels, United Kingdom.

EMA/PDCO/403243/2021
Amsterdam, 15 October 2021

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

EMEA-001146-PIP01-11-M07

Scope of the application

Active substance(s):

Naloxegol

Invented name:

Moventig

Condition(s):

Treatment of opioid-induced constipation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Age-appropriate oral liquid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Kyowa Kirin Pharmaceutical Development Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Kyowa Kirin Pharmaceutical Development Limited submitted to the European Medicines Agency on 12 July 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0183/2012 issued on 21 August 2012, the decision P/0108/2014 issued on 5 May 2014, the decision P/0158/2016 issued on 15 June 2016, the decision P/0292/2017 issued on 4 October 2017, the decision P/0056/2019 issued on 11 February 2019, the decision P/0381/2019 issued on 4 December 2019 and the decision P/0513/2020 issued on 22 December 2020.

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

The procedure started on 17 August 2021.

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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Treatment of opioid-induced constipation

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- tablet, age-appropriate oral liquid formulation, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of opioid-induced constipation

2.1.1. Indication(s) targeted by the PIP

Treatment of opioid-induced constipation

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

From 6 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral liquid formulation

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral liquid formulation
Non-clinical studies	2	**Study 2** Pre- and postnatal development study in the rat **Study 3** Rat juvenile toxicity study
Clinical studies	1	**Study 4** Open-label, sequential, multiple oral dose, study to assess the PK and safety of naloxegol in paediatric patients receiving opioids (D3820C00016)

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:	No
Date of completion of the paediatric investigation plan:	By October 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of opioid-induced constipation

Authorised indication(s):

Moventig is indicated for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s).

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use