EMA/122322/2019

European Medicines Agency decision

P/0061/2019

of 8 March 2019

on the acceptance of a modification of an agreed paediatric investigation plan for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (EMEA-001625-PIP01-14-M02) 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/0154/2015 issued on 10 July 2015 and the decision P/0026/2017 issued on 31 January 2017,

Having regard to the application submitted by Chugai Pharma Europe Ltd on 23 October 2018 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 1 February 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 humanised anti-IL-6 receptor (IL-6R) monoclonal antibody, solution for injection, subcutaneous 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 Chugai Pharma Europe Ltd, Mulliner House, Flanders Road, Turnham Green, W4 1NN – London, United Kingdom.

EMA/PDCO/792477/2018 Corr
London, 1 February 2019

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

EMEA-001625-PIP01-14-M02

Scope of the application

Active substance(s):

Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody

Condition(s):

Treatment of neuromyelitis optica

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Chugai Pharma Europe Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chugai Pharma Europe Ltd submitted to the European Medicines Agency on 23 October 2018 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/0154/2015 issued on 10 July 2015 and the decision P/0026/2017 issued on 31 January 2017.

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

The procedure started on 4 December 2018.

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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 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 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 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

1.1. Condition

Treatment of neuromyelitis optica

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition

Treatment of neuromyelitis optica

2.1.1. Indication(s) targeted by the PIP

Treatment of neuromyelitis optica and neuromyelitis optica spectrum disorders

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of solution for injection for subcutaneous use appropriate for the paediatric population from 2 years of age
Non-clinical studies	1	**Study 2** Reprotox enhanced pre- and postnatal development study in cynomolgus monkeys
Clinical studies	3	**Study 3** Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety and efficacy of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody

		as add-on to baseline immunosuppressant therapy in children from 12 to less than 18 years of age (and in adults) with relapsing neuromyelitis optica and neuromyelitis optica spectrum disorders (NMO/NMOSD) **Study 7** Open-label, uncontrolled trial to evaluate pharmacokinetics, safety and efficacy of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (SA237) in adolescents from 12 to less than 18 years of age (and adults) with neuromyelitis optica and neuromyelitis optica spectrum disorders (NMO/NMOSD) **Study 4** Open-label, uncontrolled trial to evaluate pharmacokinetics, activity and safety of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody in children from 2 to less than 12 years of age with relapsing neuromyelitis optica and neuromyelitis optica spectrum disorders (NMO/NMOSD)
Extrapolation, modelling and simulation studies	3	**Study 5** Modelling and simulation study to evaluate the dose of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody in the treatment of relapsing NMO/NMOSD in children from 2 to less than 12 years of age **Study 8** Analysis of existing data on efficacy, safety and pharmacokinetics of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody to evaluate the use of the product in the treatment of relapsing NMO/NMOSD in children from 12 to less than 18 years of age **Study 6** Analysis of existing data on efficacy, safety and pharmacokinetics of humanised anti-IL-6 receptor (IL-6R) monoclonal antibody to evaluate the use of the product in the treatment of relapsing NMO/NMOSD in children from 2 to less than 12 years of age
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 September 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes