EMA/382979/2015

European Medicines Agency decision

P/0154/2015

of 10 July 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (EMEA-001625-PIP01-14) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (EMEA-001625-PIP01-14) 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 application submitted by Chugai Pharma Europe Ltd on 6 June 2014 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 May 2015, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for humanised anti-IL-6 receptor (IL-6R) monoclonal antibody, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Chugai Pharma Europe Ltd, Mulliner House, Flanders Road Turnham Green, W4 1NN - London, United Kingdom.

Done at London, 10 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/154771/2015
London, 22 May 2015

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001625-PIP01-14

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 16(1) of Regulation (EC) No 1901/2006 as amended, Chugai Pharma Europe Ltd submitted for agreement to the European Medicines Agency on 6 June 2014 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 July 2014.

Supplementary information was provided by the applicant on 2 March 2015. The applicant proposed modifications to the paediatric investigation plan.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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;
- for 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	2	**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 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	2	**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 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 June 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes