EMA/385417/2021

European Medicines Agency decision

P/0320/2021

of 13 August 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083) (EMEA-002886-PIP01-20) 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 application submitted by Kyowa Kirin Pharmaceutical Development Limited on 11 September 2020 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 25 June 2021, in accordance with Article 17 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 human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083), 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 human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083), 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 human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083), 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 Kyowa Kirin Pharmaceutical Development Limited, Galabank Business Park, TD1 1QH – Galashiels, United Kingdom.

EMA/PDCO/191211/2021
Amsterdam, 25 June 2021

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

EMEA-002886-PIP01-20

Scope of the application

Active substance(s):

Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083)

Condition(s):

Treatment of atopic dermatitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Kyowa Kirin Pharmaceutical Development Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Kyowa Kirin Pharmaceutical Development Limited submitted for agreement to the European Medicines Agency on 11 September 2020 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 13 October 2020.

Supplementary information was provided by the applicant on 17 March 2021. The applicant proposed modifications to the paediatric investigation plan and to the waiver.

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 17(1) 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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)

Waiver

1.1. Condition:

Treatment of atopic dermatitis

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of atopic dermatitis

2.1.1. Indication targeted by the PIP

Treatment of moderate to severe atopic dermatitis (AD) with or without topical corticosteroids

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

From 6 months of age to less than 18 years of age.

2.1.3. Pharmaceutical form

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Compatibility study of the solution for injection to ensure that the dosage preparation procedure and presentation is age appropriate
Non-clinical studies	1	**Study 2 (SBL303-238)** Enhanced pre- and postnatal development reproductive toxicity study
Clinical studies	4	**Study 3** A randomized, double-blind, placebo-controlled, parallel group study to investigate the efficacy and safety of KHK4083 in combination with topical corticosteroids in adolescents age 12 years to less than 18 years of age (and adults) with moderate to severe atopic dermatitis.

		Study 4 A randomized, double-blind, placebo-controlled, parallel group two part study to investigate the efficacy and safety of KHK4083 monotherapy in adolescents age 12 years to less than 18 years of age (and adults) with moderate to severe atopic dermatitis. **Study 5** A randomized, double-blind, placebo-controlled study to investigate the safety and efficacy of KHK4083 in combination with topical corticosteroids (TCS) in subjects aged 6 years to less than 12 years with moderate to severe atopic dermatitis. **Study 6** A two part open label dose finding (Part A) and randomised, double blind, placebo controlled study (Part B) to investigate pharmacokinetics (PK), pharmacodynamics (PD), safety and efficacy, of KHK4083 in combination with topical corticosteroids (TCS) in children aged 6 months to less than 6 years, with moderate to severe atopic dermatitis.
Extrapolation, modelling and simulation studies	1	**Study 7** Modelling and simulation study to evaluate the use of the product in the treatment of moderate to severe atopic dermatitis in children from 6 months to less than 18 years of age with moderate to severe atopic dermatitis.
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 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes