EMA/26711/2020

European Medicines Agency decision

P/0055/2020

of 10 February 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human immunoglobulin G2 isotype antibody to IL-33R (EMEA-002515-PIP01-18) 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 GlaxoSmithKline Trading Services Limited on 18 January 2019 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 11 December 2019, 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 immunoglobulin G2 isotype antibody to IL-33R, powder for solution for injection, intravenous 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 immunoglobulin G2 isotype antibody to IL-33R, powder for solution for injection, intravenous 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 immunoglobulin G2 isotype antibody to IL-33R, powder for solution for injection, intravenous 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 GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

EMA/PDCO/510198/2019
Amsterdam, 11 December 2019

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

EMEA-002515-PIP01-18

Scope of the application

Active substance(s):

Human immunoglobulin G2 isotype antibody to IL-33R

Condition(s):

Treatment of asthma

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted for agreement to the European Medicines Agency on 18 January 2019 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 26 February 2019.

Supplementary information was provided by the applicant on 5 September 2019. The applicant proposed modifications to the paediatric investigation plan.

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)(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 asthma

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- powder for solution for injection, intravenous 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 asthma

2.1.1. Indication(s) targeted by the PIP

Add-on asthma treatment for patients aged 6-11 years currently uncontrolled on FP ≥200µg/day (or equivalent) plus another controller

Add-on asthma treatment for patients 12 years and above currently uncontrolled on medium/high dose ICS/LABA (FP equivalent ≥500µg/day) plus another controller

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

From 6 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	1	**Study 1** Reprotox: (enhanced) pre- and postnatal development study in monkeys
Clinical studies	4	**Study 2** (209636) Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy and multiple dose regimens of

		GSK3772847 as add-on to standard of care in children from 12 to less than 18 years of age (and adults) with moderate-severe uncontrolled asthma **Study 3** (209678) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of GSK3772847 as add-on to standard of care in children from 12 to less than 18 years of age (and adults) with moderate-severe uncontrolled asthma **Study 4** (209679) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of GSK3772847 in reducing oral corticosteroid (OCS) use in children from 12 to less than 18 years of age (and adults) with steroid dependent severe asthma **Study 5** Double-blind, randomised, placebo-controlled trial to evaluate PK/PD, safety and efficacy of GSK3772847 as add-on to standard of care in children from 6 to less than 12 years of age with moderate-severe uncontrolled asthma
Extrapolation, modelling and simulation studies	3	**Study 6** Population PK/PD model to integrate all available PK and PD data for use in selecting doses for Study 2, Study 3 and Study 4 **Study 7** Population PK/PD model to integrate all available PK and PD data for use in selecting doses for Study 5 **Study 8** Population PK/PD model to integrate all available PK and PD data to describe the PK and PD from 6 years and above in order to select a suitable paediatric posology
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 October 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes