

EMA/337422/2016

European Medicines Agency decision

P/0146/2016

of 27 May 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745), (EMA-001813-PIP01-15) 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 recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745), (EMA-001813-PIP01-15) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Gilead Sciences International Ltd on 4 June 2015 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 29 April 2016, 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 recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745), 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 recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745), 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 recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745), 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 Gilead Sciences International Ltd, Gilead Sciences International Ltd, Flowers Building, Granta Park, Abington, CB21 – Cambridge, United Kingdom.

Done at London, 27 May 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/108429/2016 **Corr**

London, 29 April 2016

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

EMA-001813-PIP01-15

Scope of the application

Active substance(s):

Recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745)

Condition(s):

Treatment of ulcerative colitis

Treatment of Crohn's disease

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

Gilead Sciences International Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd submitted for agreement to the European Medicines Agency on 4 June 2015 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 14 July 2015.

Supplementary information was provided by the applicant on 5 February 2016. 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 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) 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)

1. Waiver

1.1. Condition:

Treatment of ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition:

Treatment of Crohn's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- solution for injection, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active ulcerative colitis in paediatric patients aged 2 to less than 18 years of age

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	0	Not applicable.
Non-clinical studies	1	Study 1: Pre and postnatal development study to determine toxicity and toxicokinetics in the rat (TX-296-2011)
Clinical studies	1	Study 2: Randomised, double-blind, placebo-controlled, maintenance study to evaluate pharmacokinetics, safety, tolerability and efficacy of GS-5745 in children and adolescents 2 to less than 18 years old with moderately to severely active ulcerative colitis. (GS-US-326-1859)
Extrapolation, modelling and simulation studies	1	Study 4: Modelling and simulation study to evaluate the use of the product in the treatment of ulcerative colitis in children from 2 years to less than 18 years of age using information from GS-5745 adult development programme.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of Crohn's disease

2.2.1. Indication(s) targeted by the PIP

Treatment of moderately to severely active Crohn's disease in paediatric patients aged 2 to less than 18 years of age

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

From 2 to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for injection

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	Study 1: As for condition treatment of ulcerative colitis
Clinical studies	1	Study 3: Randomised, double-blind, placebo-controlled, maintenance study to evaluate pharmacokinetics, safety, tolerability and efficacy of GS-5745 in children and adolescents 2 to less than 18 years old with moderately to severely active Crohn's disease. (GS-US-326-1858)
Extrapolation, modelling and simulation studies	1	Study 5: Modelling and simulation study to evaluate the use of the product in the treatment of Crohn's disease in children from 2 years to less than 18 years of age using information from GS-5745 adult development programme.
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 December 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes