EMA/900716/2018

European Medicines Agency decision

P/0045/2019

of 29 January 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for filgotinib (EMEA-001619-PIP03-16) 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 Gilead Sciences International Ltd. on 5 August 2016 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 14 December 2018, 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 filgotinib, film-coated tablet, age-appropriate oral dosage form, oral 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 filgotinib, film-coated tablet, age-appropriate oral dosage form, oral 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 filgotinib, film-coated tablet, age-appropriate oral dosage form, oral 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., Flowers Building, Granta Park, Abington, CB21 6GT - Cambridge, United Kingdom.

EMA/PDCO/638470/2018
London, 14 December 2018

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

EMEA-001619-PIP03-16

Scope of the application

Active substance(s):

Filgotinib

Condition(s):

Treatment of ulcerative colitis

Treatment of Crohn's disease

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral 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 5 August 2016 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 September 2016.

Supplementary information was provided by the applicant on 10 September 2018. 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 ulcerative colitis

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- film-coated tablet, age-appropriate oral dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition

Treatment of Crohn's disease

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- film-coated tablet, age-appropriate oral dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients 2 years of age and older with moderately-to-severely active ulcerative colitis

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

From 2 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** Development of a reduced-strength film-coated tablet. **Study 2** Development of an age-appropriate oral dosage form.
Non-clinical studies	1	**Study 3** Toxicity study of filgotinib and its metabolite GS-829845 in juvenile rats.
Clinical studies	1	**Study 4 (GS-US-418-4113)** Double-blind, placebo controlled study to evaluate pharmacokinetics, efficacy, safety and tolerability of a 58 week course of filgotinib in paediatric subjects from 2 years to less than 18 years of age with ulcerative colitis.
Extrapolation, modelling and simulation studies	1	**Study 5** Modelling and simulation study to investigate the dose selection for the use of filgotinib in children from 2 years to less than 18 years of age with ulcerative colitis.
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 paediatric patients 2 years of age and older with moderately-to-severely active Crohn's disease

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

From 2 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** *As for condition treatment of ulcerative colitis* **Study 2** *As for condition treatment of ulcerative colitis*
Non-clinical studies	2	**Study 3** *As for condition treatment of ulcerative colitis*
Clinical studies	1	**Study 6 (GS-US-419-4114)** Double-blind, placebo-controlled study to evaluate pharmacokinetics, efficacy, safety and tolerability of a 58 week course of filgotinib in paediatric subjects from 2 years to less than 18 years of age with Crohn's disease.
Extrapolation, modelling and simulation studies	1	**Study 7** Modelling and simulation study to investigate the dose selection for the use of filgotinib in children from 2 years to less than 18 years of age with Crohn's disease.
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 March 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes