EMA/492440/2020

European Medicines Agency decision

P/0386/2020

of 25 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for filgotinib (EMEA-001619-PIP03-16-M01) 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 acceptance of a modification of an agreed paediatric investigation plan for filgotinib (EMEA-001619-PIP03-16-M01) 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 European Medicines Agency's decision P/0045/2019 issued on 29 January 2019,

Having regard to the application submitted by Gilead Sciences International Ltd. on 13 July 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 4 September 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for filgotinib, film-coated tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0371/2018 issued on 6 December 2018, including subsequent modifications thereof.

Article 3

This decision is addressed to Gilead Sciences International Ltd., Flowers Building, Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

EMA/PDCO/399312/2020 Corr
Amsterdam, 4 September 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001619-PIP03-16-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd. submitted to the European Medicines Agency on 13 July 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0045/2019 issued on 29 January 2019.

The application for modification proposed introduction of a cross reference to another agreed paediatric investigation plan for the same product.

The procedure started on 18 August 2020.

Scope of the modification

Introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in the conditions treatment of ulcerative colitis and treatment of Crohn's disease, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0371/2018 issued on 6 December 2018.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to introduction of a cross reference to all indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals in the conditions treatment of ulcerative colitis and treatment of Crohn's disease, covered by a separate agreed paediatric investigation plan as set out in the EMA decision P/0371/2018 issued on 6 December 2018.

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

2. The measures and timelines of the 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	1	**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