EMA/561838/2023

European Medicines Agency decision

P/0526/2023

of 29 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for filgotinib (Jyseleca), (EMEA-001619-PIP03-16-M02) 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 Union procedures for the authorisation and supervision of medicinal products for human 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 and the decision P/0386/2020 issued on 25 September 2020,

Having regard to the application submitted by Galapagos NV on 27 July 2023 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 10 November 2023, 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 and to the deferral and to the waiver.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for filgotinib (Jyseleca), film-coated tablet, oral use, including changes to the deferral and to the waiver, 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/0273/2017 issued on 4 October 2017, including subsequent modifications thereof.

Article 3

This decision is addressed to Galapagos NV, Generaal De Wittelaan L11 A3, 2800 – Mechelen, Belgium.

EMA/PDCO/373301/2023
Amsterdam, 10 November 2023

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

EMEA-001619-PIP03-16-M02

Scope of the application

Active substance(s):

Filgotinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ulcerative colitis

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Galapagos NV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Galapagos NV submitted to the European Medicines Agency on 27 July 2023 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 and the decision P/0386/2020 issued on 25 September 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

The procedure started on 11 September 2023.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

A waiver for a new paediatric subset was added.

A pharmaceutical form was deleted.

The scope of the Paediatric Investigation Plan was amended to exclude a condition.

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 changes to the paediatric investigation plan and to the deferral and to the waiver in the scope set out in the Annex I of this opinion;

   The Paediatric Committee member of Norway 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 annexes 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 8 years of age;
- film-coated tablet, age-appropriate oral dosage form, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition

Treatment of ulcerative colitis

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients 8 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 8 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of a reduced-strength film-coated tablet. **Study 2** *(study deleted in procedure EMEA-001619-PIP03-16-M02)*
Non-clinical studies	**Study 3** Toxicity study of filgotinib and its metabolite GS-829845 in juvenile rats.
Clinical studies	**Study 4 (GLPG0634-CL-331)** Single-arm study to evaluate activity, safety, tolerability and pharmacokinetics of a 58 week course of filgotinib in paediatric subjects from 8 years to less than 18 years of age with ulcerative colitis.
Extrapolation, modelling and simulation studies	**Study 5** Modelling and simulation study to investigate the dose selection for the use of filgotinib in children from 8 years to less than 18 years of age with ulcerative colitis.
Other studies	Not applicable.
Other measures	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 2029.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of rheumatoid arthritis

   Authorised indication(s):

   - Treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX)
     - Invented name(s): Jyseleca
     - Authorised pharmaceutical form(s): Film-coated tablet
     - Authorised route(s) of administration: Oral use
     - Authorised via centralised procedure

2. Treatment of ulcerative colitis

   Authorised indication(s):

   - Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.
     - Invented name(s): Jyseleca
     - Authorised pharmaceutical form(s): Film-coated tablet
     - Authorised route(s) of administration: Oral use
     - Authorised via centralised procedure