EMA/114605/2024

European Medicines Agency decision

P/0119/2024

of 12 April 2024

on the acceptance of a modification of an agreed paediatric investigation plan for filgotinib (Jyseleca), (EMEA-001619-PIP04-17-M03) 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/0273/2017 issued on 4 October 2017, decision P/0371/2018 issued on 6 December 2018 and the decision P/0113/2023 issued on 13 April 2023,

Having regard to the application submitted by Galapagos NV on 17 November 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 23 February 2024, 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, 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, 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 is addressed to Galapagos NV Generaal, De Wittelaan L11 A3, 2800 – Mechelen, Belgium.

EMA/PDCO/535265/2023 Corr[1]
Amsterdam, 23 February 2024

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

EMEA-001619-PIP04-17-M03

Scope of the application

Active substance(s):

Filgotinib

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

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 17 November 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/0273/2017 issued on 4 October 2017, decision P/0371/2018 issued on 6 December 2018 and the decision P/0113/2023 issued on 13 April 2023.

The application for modification proposed changes to the agreed paediatric investigation.

The procedure started on 3 January 2024.

[1] 5 April 2024

Scope of the modification

Some measures and timelines of the paediatric investigation plan have been modified.

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 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 chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- film-coated tablet, age-appropriate oral dosage form, oral 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).

The waiver applies to:

- the paediatric population from 1 year 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 chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis

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** This study was deleted as a result of procedure EMEA-001619-PIP04-17-M02. **Study 2** Development of reduced-strength film-coated tablet.

Non-clinical studies	**Study 3** Toxicity study of filgotinib and its metabolite GS-829845 in juvenile rats.
Clinical studies	**Study 4** Double-blind, randomised, placebo-controlled trial to evaluate efficacy, safety and pharmacokinetics of filgotinib in children and adolescents from 8 years to less than 18 years of age with polyarticular-course juvenile idiopathic arthritis (pJIA). (GLPG0634-CL-329) **Study 5** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of filgotinib in children and adolescents from 8 years to less than 18 years of age with systemic-onset juvenile idiopathic arthritis (sJIA). **Study 7** Open-label, multiple dose study to evaluate pharmacokinetics, safety, and tolerability of filgotinib in children and adolescents from 8 years to less than 18 years of age with juvenile idiopathic arthritis (JIA).
Extrapolation, modelling and simulation studies	**Study 6** Modelling and simulation study to investigate the dose selection for the use of filgotinib in children and adolescents from 8 years to less than 18 years of age with juvenile idiopathic arthritis (JIA).
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 December 2027
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

- 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