MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-101304-PIP01-23-M01

Scope of the Application

Active Substance(s)

FILGOTINIB MALEATE

Condition(s)

Treatment of ulcerative colitis

Pharmaceutical Form(s)

Film-coated tablet. Age-appropriate oral dosage form.

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Galapagos NV

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Galapagos NV submitted to the licensing authority on 12/12/2023 15:58 GMT an application for a Modification

The procedure started on 21/02/2024 17:12 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101304-PIP01-23-M01

Of 27/02/2024 17:57 GMT

On the adopted decision for FILGOTINIB MALEATE (MHRA-101304-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for FILGOTINIB MALEATE, Film-coated tablet Age-appropriate oral dosage form , ORAL USE .

This decision is addressed to Galapagos NV, Generaal De Wittelaan L11 A3, Mechelen, BELGIUM, 2800

ANNEX I

1. Waiver

1.1 Condition:

Treatment of ulcerative colitis. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 8 years of age. Pharmaceutical form(s): Film-coated tablet. Age-appropriate oral dosage form. Route(s) of administration: ORAL USE. Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of ulcerative colitis. ‘Treatment of Crohn's disease’, and related Studies 6 and 7 were deleted during procedure MHRA-101304-PIP01-23-M01.

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients 8 years of age and older with moderately to severely active ulcerative colitis.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 8 years of age to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet. Age-appropriate oral dosage form.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a reduced-strength film-coated tablet. Study 2, deleted during procedure MHRA-101304-PIP01-23-M01.
Non-Clinical Studies	1	Study 3 Toxicity study of filgotinib and its metabolite GS-829845 in juvenile rats.
Clinical Studies	1	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 pf age to less than 18 years of age with ulcerative colitis.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Modelling and simulation study to investigate the dose selection for the use of filgotinib in children from 8 years of age to less than 18 years of age with ulcerative colitis.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/06/2029

Deferral of one or more studies contained in the paediatric investigation plan:	Yes