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 (MHRA-101021-PIP01-23-M02) and to the deferral

MHRA-101021-PIP01-23-M03

Scope of the Application

Active Substance(s)

FILGOTINIB MALEATE

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

Alfasigma S.p.A.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alfasigma S.p.A. submitted to the licensing authority on 15/05/2025 09:47 BST an application for a Modification

The procedure started on 12/06/2025 09:39 BST

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-101021-PIP01-23-M03

Of 24/06/2025 15:29 BST

On the adopted decision for FILGOTINIB MALEATE (MHRA-101021-PIP01-23-M03) 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 , ORAL USE .

This decision is addressed to Alfasigma S.p.A., Via Ragazzi del '99, n. 5, Bologna, ITALY, 40133

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis). 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 Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 1 year of age 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). For the paediatric population from 1 year to less than 8 years of age on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

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

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis.

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

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

2.4 Pharmaceutical Form(s):

Film-coated tablet.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1, Deleted in procedure MHRA-101021-PIP01-23-M01. Study 2 Development of reduced-strength film-coated tablet.
Non-Clinical Studies	1	Study 3 Toxicity study of filgotinib and its metabolite GS-829845 in juvenile rats.
Clinical Studies	3	Study 4 (GLPG0634-CL-329) Open-label study to evaluate safety, tolerability, pharmacokinetics and efficacy of filgotinib in children and adolescents from 8 years to less than 18 years of age with polyarticular-course juvenile idiopathic arthritis (pJIA). 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 (GLPG0634-CL-131) Added in procedure MHRA-101021-PIP01-23-M01. 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 polyarticular-course juvenile idiopathic arthritis (pJIA).

Extrapolation, Modeling & Simulation Studies	1	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	0	Not applicable.
Other Measures	1	At least the adult phase 3 studies GS-US-417-0301, GS-US-417-0302, and GS-US-417-0303 and the phase 2 adult studies GLPG0634-CL-201, GLPG0634-CL-202, GLPG0634-203, and GLPG0634-204 in rheumatoid arthritis and studies 4, 6 and 7 of this PIP are part of an extrapolation plan covering the paediatric population from 8 years to less than 18 years of age with polyarticular-course JIA, as agreed by the Regulatory Agency.

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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes