

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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102558-PIP01-26

Scope of the Application

Active Substance(s)

Brepocitinib

Condition(s)

Treatment of idiopathic inflammatory myopathies

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

TMC Pharma Services Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, TMC Pharma Services Limited submitted to the licensing authority on 22/07/2026 10:06 BST an application for a Paediatric Investigation Plan

The procedure started on 04/08/2026 15:29 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-102558-PIP01-26

Of 18/09/2026 08:53 BST

On the adopted decision for Brepocitinib (MHRA-102558-PIP01-26) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Brepocitinib, Tablet , Oral use .

This decision is addressed to TMC Pharma Services Limited, Lodge Farm Barn, Elvetham Park Estate, Fleet Road, Hartley Wintney, UNITED KINGDOM, RG278AS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of idiopathic inflammatory myopathies The waiver applies / applied to: Paediatric
Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s):
Tablet 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 idiopathic inflammatory myopathies

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile dermatomyositis

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

The paediatric population from 12 years birth to less than 18 years of age
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2.4 Pharmaceutical Form(s):

Tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open-label, uncontrolled, multiple-dose trial to evaluate pharmacokinetics, safety, activity, acceptability and palatability of brepocitinib as add-on to standard of care in children from 12 years to less than 18 years of age with idiopathic inflammatory myopathy to support extrapolation of efficacy from adult studies.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population pharmacokinetic study to support dose recommendation in children from 12 years to less than 18 years of age with dermatomyositis. Extrapolation Plan Studies 1 and 2 are part of the extrapolation plan of efficacy data from adults to adolescents from 12 years to less than 18 years of age with juvenile dermatomyositis.
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:	31/03/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

