MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101552-PIP01-24

Scope of the Application

Active Substance(s)

litifilimab

Condition(s)

Treatment of lupus erythematosus

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVENOUS

Name / Corporate name of the PIP applicant

Biogen Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Biogen Netherlands B.V. submitted to the licensing authority on 29/11/2024 14:28 GMT an application for a Paediatric Investigation Plan

The procedure started on 13/01/2025 19:05 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 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-101552-PIP01-24

Of 15/09/2025 20:08 BST

On the adopted decision for litifilimab (MHRA-101552-PIP01-24) 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 litifilimab, Solution for injection , INTRAVENOUS USE .

This decision is addressed to Biogen Netherlands B.V., Prins Mauritslaan 13, Badhoevedorp, NETHERLANDS, 1171 LP

ANNEX I

1. Waiver

1.1 Condition:

Treatment of lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment of active systemic lupus erythematosus in patients receiving nonbiologic lupus standard of care

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

The paediatric population from 5 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a pre-filled syringe for accurate administration of smaller doses
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, efficacy and safety of litifilimab in children from 5 years to less than 18 years of age with systemic lupus erythematosus.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Modelling and simulation study to evaluate the use of litifilimab in the treatment of systemic lupus erythematosus in children from 5 years to less than 18 years of age
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:	No
Date of completion of the paediatric investigation plan:	31/12/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes