MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-101619-PIP01-24

Scope of the Application

Active Substance(s)

SPESOLIMAB

Condition(s)

Treatment of hidradenitis suppurativa

Pharmaceutical Form(s)

Solution for infusion, Solution for injection

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Boehringer Ingelheim International GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Boehringer Ingelheim International GmbH submitted to the licensing authority on 16/09/2024 12:43 BST an application for a Paediatric Investigation Plan

The procedure started on 05/11/2024 07:47 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-101619-PIP01-24

Of 21/01/2025 15:07 GMT

On the adopted decision for SPESOLIMAB (MHRA-101619-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 SPESOLIMAB, Solution for infusion, Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS USE .

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, Ingelheim am Rhein, GERMANY, 55216

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hidradenitis suppurativa The waiver applies / applied to: Paediatric Subset(s): The paediatric population prior to the onset of puberty (Tanner stage less than 2) Pharmaceutical form(s): Solution for infusion Solution for injection Route(s) of administration: INTRAVENOUS USE SUBCUTANEOUS USE Reason for granting waiver: 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).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hidradenitis suppurativa

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe hidradenitis suppurativa in adolescents and children with Tanner stage $\geq$ 2

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

The paediatric population from onset of puberty (Tanner stage 2) to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for infusion Solution for injection

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 (1368-HS-Ped1) Open label trial to evaluate the pharmacokinetics (PK), safety, activity and tolerability of spesolimab in patients after the onset of puberty (with Tanner stage 2 or above) to less than 18 years of age with moderate to severe hidradenitis suppurativa (HS).
Extrapolation, Modeling & Simulation Studies	2	Study 2 (M&S 1) Study optimisation, to inform paediatric study design. Study 3 (M&S 2) Dose finding modelling and simulation study to evaluate adequacy of dosing in paediatric patients after the onset of puberty (with Tanner stage 2 or above) to less than 18 years of age with moderate to severe HS.
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:	30/04/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes