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-100463-PIP01-22-M01

Scope of the Application

Active Substance(s)

spesolimab

Condition(s)

Treatment of Generalised Pustular Psoriasis, Prevention of Generalised Pustular Psoriasis

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 17/03/2022 13:21 GMT an application for a Modification

The procedure started on 14/11/2022 08:17 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

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-100463-PIP01-22-M01

Of 13/12/2022 15:48 GMT

On the adopted decision for spesolimab (MHRA-100463-PIP01-22-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 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 Generalised Pustular Psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age 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 specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible. 1.Waiver 1.2 Condition: Prevention of Generalised Pustular Psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age 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 specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of Generalised Pustular Psoriasis Condition 2: Prevention of Generalised Pustular Psoriasis

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of acute or chronic Generalised Pustular Psoriasis (GPP) and for the prevention of flares. Condition 2: Treatment of acute or chronic Generalised Pustular Psoriasis (GPP) and for the prevention of flares.

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

For both Conditions : The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

For both Conditions : 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	(Same Study for both Conditions) Study 1 (1368-0027) Randomised parallel groups, double blind, placebo-controlled study to evaluate the efficacy and safety of spesolimab compared to placebo in adolescents from 12 years to less than 18 years of age (and adults) with generalised pustular psoriasis.
Extrapolation, Modeling & Simulation Studies	2	(Same Studies for both Conditions) Study 2 Dose Finding population PK study. Study 3 Dose Finding population PK/PD model.
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:	30/04/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes