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-100894-PIP01-23

Scope of the Application

Active Substance(s)

Depemokimab

Condition(s)

Treatment of Eosinophilic granulomatosis with polyangiitis (EGPA)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 01/03/2023 12:57 GMT an application for a Paediatric Investigation Plan

The procedure started on 05/07/2023 16:59 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-100894-PIP01-23

Of 09/10/2023 09:05 BST

On the adopted decision for Depemokimab (MHRA-100894-PIP01-23) 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 Depemokimab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

2.2 Indication(s) targeted by the PIP:

Add-on treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in patients 6 years of age and older

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

The paediatric population from 6 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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (218628) Open-label, single arm study to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of depemokimab in paediatric participants from 6 years to less than 18 years of age with relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA) receiving standard of care (SoC) therapy.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation population pharmacokinetic (PK) and pharmacodynamic (PD) study to evaluate the use of the product in the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in children from 6 year to less than 18 years of age. Extrapolation Plan Studies 1 and 2 are part of the extrapolation plan of efficacy data from adult to the paediatric population from 6 years to less than 18 years of age with condition EGPA.
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:	31/01/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes