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-100961-PIP01-23

Scope of the Application

Active Substance(s)

Depemokimab

Condition(s)

Treatment of hypereosinophilic syndrome (HES)

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 14/04/2023 16:19 BST an application for a Paediatric Investigation Plan

The procedure started on 26/09/2023 08:04 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-100961-PIP01-23

Of 11/09/2024 07:35 BST

On the adopted decision for Depemokimab (MHRA-100961-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, GlaxoSmithKline UK Limited, Middlesex, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hypereosinophilic syndrome (HES) 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 hypereosinophilic syndrome (HES)

2.2 Indication(s) targeted by the PIP:

Treatment of hypereosinophilic syndrome

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 (218626) Open-label, uncontrolled, single arm study to evaluate pharmacokinetics (PK), safety and pharmacodynamics (PD) of depemokimab in children and adolescents from 6 years to less than 18 years of age with hypereosinophilic syndrome.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation population PK and PD study, to evaluate the use of the product in the treatment of hypereosinophilic syndrome in children and adolescents from 6 years to less than 18 years of age. Extrapolation plan Studies 1 and 2 are part of the extrapolation plan of efficacy based on population pharmacokinetics (PK) and population PK/pharmacodynamics (PD) models and clinical data from adults with HES (source population) to children and adolescents with HES aged 6 years to less than 18 years (target population).
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:	31/08/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes