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-100364-PIP01-21) and to the deferral

MHRA-100364-PIP01-21-M01

Scope of the Application

Active Substance(s)

Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E

Condition(s)

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Pharmaceutical Form(s)

Powder and suspension for suspension for injection

Route(s) of Administration

INTRAMUSCULAR 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 21/12/2023 11:02 GMT an application for a Modification

The procedure started on 12/02/2024 11:18 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 and to the deferral

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-100364-PIP01-21-M01

Of 19/04/2024 09:15 BST

On the adopted decision for Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E (MHRA-100364-PIP01-21-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 Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E, Powder and suspension for suspension for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Powder and suspension for suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder and suspension for suspension 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	2	Study 1 (RSV OA=ADJ-015) Randomised-controlled, observer-blind study with age-de- escalation, dose-escalating step, to assess the non-inferiority of the immune response and safety of one dose of RSVPreF3 OA investigational vaccine in children and adolescents with chronic conditions at increased risk of Respiratory Syncytial Virus (RSV) lower respiratory tract disease. Study 2 (RSV OA=ADJ-016) Open-label study to assess the immunogenicity, reactogenicity and safety of Respiratory Syncytial Virus (RSV) PreF3 OA investigational vaccine in immunocompromised children and adolescents at risk of lower respiratory tract disease.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	30/04/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes