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-100364-PIP01-21

Scope of the Application

Active Substance(s)

Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein

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 24/11/2021 14:58 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/04/2022 17:30 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-100364-PIP01-21

Of 28/04/2022 08:30 BST

On the adopted decision for Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein/AS01 (MHRA-100364-PIP01-21) 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 Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein/AS01, Powder and suspension for suspension for injection , Intramuscular use .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road, 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) Open-label controlled study to assess the immunogenicity, reactogenicity and safety of Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein/AS01 vaccine in children and adolescents with chronic conditions at risk of 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 recombinant Fusion protein/AS01 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