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-100519-PIP01-22

Scope of the Application

Active Substance(s)

RSV preF protein

Condition(s)

Prevention of lower respiratory tract disease caused by Respiratory syncytial virus (RSV)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Janssen-Cilag UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag UK Ltd submitted to the licensing authority on 23/06/2022 01:03 BST an application for a

The procedure started on 31/08/2022 09:58 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-100519-PIP01-22

Of 25/11/2022 14:34 GMT

On the adopted decision for RSV preF protein (MHRA-100519-PIP01-22) 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 for RSV preF protein, Solution for injection , INTRAMUSCULAR USE .

This decision is addressed to Janssen-Cilag UK Ltd, 50-100 Holmers Farm way, High Wycombe , UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution 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 (RSV)

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children from 2 years to less than 18 years at increased risk of severe RSV disease.

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):

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	3	Study 1 Randomised, double-blind, controlled trial to evaluate the reactogenicity, safety and immunogenicity of RSV preF protein (used in combination with Ad26.RSV.preF) in children and adolescents from 2 years to less than 18 years of age at increased risk of severe RSV disease. Study 2 Double-blind controlled trial to evaluate the reactogenicity, safety and immunogenicity of RSV preF protein (used in combination with Ad26.RSV.preF) in children and adolescents from 2 years to less than 18 years of age at increased risk of severe RSV disease. Study 3 Open-label trial to evaluate the reactogenicity, safety and immunogenicity of RSV preF protein (used in combination with Ad26.RSV.preF) in immunocompromised children and adolescents from 2 years to less than 18 years of age.
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:	31/03/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes