MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100636-PIP01-22-M01

Scope of the Application

Active Substance(s)

Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain

Condition(s)

Prevention of lower respiratory tract disease (LRTD) 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 Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen Cilag Ltd submitted to the licensing authority on 05/08/2022 13:59 BST an application for a Modification

The procedure started on 31/08/2022 11:02 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 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.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-100636-PIP01-22-M01

Of 16/11/2022 13:33 GMT

On the adopted decision for Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain (MHRA-100636-PIP01-22-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 Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain, Solution for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

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

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in children at increased risk of severe RSV disease

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

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	5	Study 1(VAC18194RSV2001) Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain (Ad26.RSV.preF) in healthy RSV seropositive toddlers from 12 to 24 months of age (and adults). Study 2 (VAC18194RSV2002) Observer-blind, randomised, controlled trial to evaluate safety, reactogenicity and immunogenicity of Ad26.RSV.preF in healthy RSV seronegative toddlers from 12 to 24 months of age. Study 3 (VAC18194RSV2003) Deleted during procedure MHRA-100636-PIP01-22-M01 Study 4 (VAC18194RSV2004) Deleted during procedure MHRA-100636-PIP01-22-M01

		Study 5 (VAC18194RSV3001) Deleted during procedure MHRA-100636-PIP01-22-M01 Study 6 (VAC18194RSV4001) Deleted during procedure MHRA-100636-PIP01-22-M01 Study 7 (VAC18194RSV4002) Deleted during procedure MHRA-100636-PIP01-22-M01 Study 8 (VAC18194RSV4003) Deleted during procedure MHRA-100636-PIP01-22-M01 (Studies 9, 10 and 11 added during procedure MHRA-100636-PIP01-22-M01) Study 9 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 with chronic conditions at risk of lower respiratory tract disease. Study 10 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 11 Open-label controlled 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:	Yes
Date of completion of the paediatric investigation plan:	31/03/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes