EMA/824453/2022

European Medicines Agency decision

P/0442/2022

of 28 October 2022

on the acceptance of a modification of an agreed paediatric investigation plan 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 (EMEA-002172-PIP02-17-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0318/2018 issued on 12 September 2018 and the decision P/0197/2020 issued on 20 May 2020,

Having regard to the application submitted by Janssen-Cilag International NV on 30 May 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 September 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan 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, suspension for injection, intramuscular use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

A waiver 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, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Janssen-Cilag International NV, 30 Turnhoutseweg, 2340 - Beerse, Belgium.

EMA/PDCO/566888/2022 Corr
Amsterdam, 9 August 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002172-PIP02-17-M02

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 caused by respiratory syncytial virus (RSV)

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 30 May 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0318/2018 issued on 12 September 2018 and the decision issued on 20 May 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver.

The procedure started on 11 July 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

A waiver for a new paediatric subset has been added.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

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

The waiver applies to:

- the paediatric population from birth to less than 1 year;
- suspension for injection, intramuscular use;
- 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

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

2.1.1. Indication(s) targeted by the PIP

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

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 4** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 5** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 6** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 7** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 8** *deleted in modification EMEA-002172-PIP02-17-M02* **Study 9** *added in modification EMEA-002172-PIP02-17-M02 (same as study 1 of EMEA-003094-PIP02-21)* 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 10** *added in modification EMEA-002172-PIP02-17-M02 (same as study 2 of EMEA-003094-PIP02-21)* 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** *added in modification EMEA-002172-PIP02-17-M02 (same as study 3 of EMEA-003094-PIP02-21)* 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, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes