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European Medicines Agency decision

P/0318/2018

of 12 September 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral 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) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Janssen-Cilag International NV on 20 October 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 July 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

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

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

Has adopted this decision:

Article 1

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

Article 2

A deferral 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, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

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

EMA/PDCO/302107/2018
London, 27 July 2018

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002172-PIP02-17

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 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 International NV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted for agreement to the European Medicines Agency on 20 October 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 28 November 2017.

Supplementary information was provided by the applicant on 04 May 2018. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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

Not applicable.

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)

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	7	**Study 1** 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) (VAC18194RSV2001). **Study 2** Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of Ad26.RSV.preF in healthy RSV-seronegative toddlers from 12 to 24 months of age (VAC18194RSV2002).

		Study 3 Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of Ad26.RSV.preF in healthy RSV-seronegative infants from 6 to 12 months of age (VAC18194RSV2003). **Study 4** Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of Ad26.RSV.preF in healthy 2-month old infants when co-administered with routine childhood vaccines (VAC18194RSV2004). **Study 5** Double-blind, randomised, placebo-controlled trial to evaluate vaccine efficacy, safety and immunogenicity of Ad26.RSV.preF in healthy 2-month old infants when co-administered with routine childhood vaccines (VAC18194RSV3001). **Study 6** Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of Ad26.RSV.preF in healthy neonates starting immunisation at birth compared to starting immunisation at 2 months of age (VAC18194RSV4001). **Study 7** Open-label, uncontrolled trial to evaluate safety, tolerability, and immunogenicity of Ad26.RSV.preF in children from birth to less than 18 years of age who are at high risk of severe RSV disease (VAC18194RSV4002). **Study 8** Double-blind, randomised, placebo-controlled trial to evaluate safety, tolerability and immunogenicity of Ad26.RSV.preF in healthy neonates starting immunisation at birth (VAC18194RSV4003).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 November 2032
Deferral for one or more measures contained in the paediatric investigation plan:	Yes