EMA/148126/2024

European Medicines Agency decision

P/0153/2024

of 6 May 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral for live attenuated respiratory syncytial virus (RSV) (EMEA-003277-PIP02-23) 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 application submitted by Sanofi Pasteur on 4 August 2023 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 March 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for live attenuated respiratory syncytial virus (RSV), nasal spray, suspension, nasal 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 live attenuated respiratory syncytial virus (RSV), nasal spray, suspension, nasal 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 – Lyon, France.

EMA/PDCO/8656/2024 Corr[1]
Amsterdam, 22 March 2024

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

EMEA-003277-PIP02-23

Scope of the application

Active substance(s):

Live attenuated respiratory syncytial virus (RSV)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of respiratory syncytial virus disease

Pharmaceutical form(s):

Nasal spray, suspension

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

Sanofi Pasteur

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted for agreement to the European Medicines Agency on 4 August 2023 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 11 September 2023.

Supplementary information was provided by the applicant on 15 December 2023.

[1] 25 April 2024.

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 Paediatric Committee member of Norway 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 annexes 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 respiratory syncytial virus (RSV) disease

2.1.1. Indication(s) targeted by the PIP

Prevention of respiratory syncytial virus (RSV) disease

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)

Nasal spray, suspension

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	**Study 1 (Reproductive and developmental toxicity study)** Reproductive and developmental toxicity study of live attenuated respiratory syncytial virus vaccine (RSVt) to evaluate the effects of vaccination on pre- and post-natal offspring development (including evaluation of teratogenicity) before mating and through mating, implantation and closure of the hard palate.
Clinical studies	**Study 2 (VAD00001)** Randomized, observer-blind, placebo-controlled, dose finding study to evaluate the safety, immunogenicity, infectivity, and virus shedding of live attenuated respiratory syncytial virus vaccine (RSVt) in infants and toddlers from 6 months of age to less than 18 months of age. **Study 3 (VAD00004)** Randomized, observer-blind, placebo-controlled, efficacy study of 2 administrations of a live attenuated respiratory syncytial virus vaccine (RSVt) in healthy infants and toddlers from 6 months of age to less than 22 months of age at enrolment, regardless of RSV serostatus.

	Study 4 (VAD00003) Observer-blind, placebo-controlled study to evaluate non-interference of prior monoclonal antibody (mAb) treatment on subsequent immune response to recombinant live-attenuated respiratory syncytial virus vaccine (RSVt) in healthy infants and toddlers from 6 months of age to less than 19 months of age, and to define an optimal time-interval between the administration of prior mAb treatment and RSVt vaccine. **Study 5 (VAD00016)** Randomized, single-blind, placebo-controlled study to evaluate non-interference of concomitant administration of routine paediatric vaccines on the antibody response of RSVt vaccine in healthy infants and toddlers 6 months of age to 12 months of age at enrolment. **Study 6 (VAD00022)** Randomized, observer blind, placebo-controlled study to assess safety, immunogenicity and infectivity of RSVt vaccine in healthy infants from birth to less than 6 months of age. **Study 7 (VAD00023)** Placebo-controlled, observer blind age de-escalating trial to evaluate the safety, immunogenicity, infectivity, and vaccine virus shedding after 2 administrations of a live attenuated RSVt vaccine in children and adolescents at high risk of severe RSV disease from birth to less than 18 years of age, including stable immunocompromised children.
Modelling and simulation analyses	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2034
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.