MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100584-PIP02-23

Scope of the Application

Active Substance(s)

Live attenuated respiratory syncytial virus (RSV)

Condition(s)

Prevention of respiratory syncytial virus (RSV) disease

Pharmaceutical Form(s)

Nasal spray, suspension

Route(s) of Administration

NASAL USE

Name / Corporate name of the PIP applicant

Sanofi Pasteur

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Pasteur submitted to the licensing authority on 14/08/2023 11:13 BST an application for a Paediatric Investigation Plan

The procedure started on 04/12/2023 07:30 GMT

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

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-100584-PIP02-23

Of 09/09/2024 09:53 BST

On the adopted decision for Live attenuated respiratory syncytial virus (RSV) (MHRA-100584-PIP02-23) 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 Paediatric Investigation Plan for Live attenuated respiratory syncytial virus (RSV), Nasal spray, suspension , NASAL USE .

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallée, Lyon, FRANCE, 69007

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of respiratory syncytial virus (RSV) disease

2.2 Indication(s) targeted by the PIP:

Prevention of respiratory syncytial virus (RSV) disease

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

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Nasal spray, suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	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	6	Study 2 (VAD00001) Randomised, 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 18 months of age. Study 3 (VAD00004) Randomised, 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) Randomised, 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 and 12 months of age at enrolment. Study 6 (VAD00022) Randomised, 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.
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:	28/02/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes