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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101360-PIP01-24-M01

Scope of the Application

Active Substance(s)

Purified Rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated)

Condition(s)

Prevention of rabies viral infection

Pharmaceutical Form(s)

Powder and solvent for suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE; INTRADERMAL 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 14/05/2024 01:30 BST an application for a Modification

The procedure started on 21/06/2024 08:05 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.

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Final Decision Letter

MHRA-101360-PIP01-24-M01

Of 15/07/2024 11:40 BST

On the adopted decision for Purified Rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated) (MHRA-101360-PIP01-24-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 Purified Rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated), Powder and solvent for suspension for injection , INTRAMUSCULAR USE; INTRADERMAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of rabies viral infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age. Pharmaceutical form(s): Powder and solvent for suspension for injection Route(s) of administration: INTRAMUSCULAR USE, INTRADERMAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of rabies viral infection.

2.2 Indication(s) targeted by the PIP:

Prevention of rabies in pre- and post-exposure prophylaxis.

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):

Powder and solvent for 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	4	Study 1 (VRV06) Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a pre-exposure regimen of an earlier formulation of purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain) [hereafter referred to as VRVg-1] compared to Imovax rabies vaccine in healthy children and adolescents from 2 years to less than 18 years of age. Study 2 (VRV08) Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a simulated post-exposure regimen of VRVg-1 compared to Verorab rabies vaccine in healthy children and adolescents from 10 years to less than 18 years of age (and adults). Study 3 (VRV12) Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a pre-exposure regimen of purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain) [hereafter referred to as VRVg-2] compared to Verorab or Imovax rabies vaccine in healthy children and adolescents from 1

		year to less than 18 years of age (and adults). Study 4 (VRV09) Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of two post-exposure regimens of VRVg-2 compared to Verorab vaccine in healthy children and adolescents from 1 year to less than 18 years of age (and adults).
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:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	No