MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-100754-PIP01-22

Scope of the Application

Active Substance(s)

Live-attenuated La Reunion strain of chikungunya virus

Condition(s)

Prevention of chikungunya virus disease

Pharmaceutical Form(s)

Powder and solvent for suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Valneva Austria GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Valneva Austria GmbH submitted to the licensing authority on 15/11/2022 15:51 GMT an application for a

The procedure started on 26/07/2023 15:32 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 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-100754-PIP01-22

Of 09/10/2023 12:25 BST

On the adopted decision for Live-attenuated La Reunion strain of chikungunya virus (MHRA-100754-PIP01-22) 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 for Live-attenuated La Reunion strain of chikungunya virus , Powder and solvent for suspension for injection , INTRAMUSCULAR .

This decision is addressed to Valneva Austria GmbH , Campus Vienna Biocenter 3, Vienna, AUSTRIA, 1030

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of chikungunya virus disease

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of disease caused by chikungunya virus live-attenuated vaccine for prophylaxis against Chikungunya disease

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

All subsets of the paediatric population from birth 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	5	Study 1 (VLA1553-321) Randomised, double-blinded, multicentre study to evaluate the immunogenicity and safety of the adult dose of VLA1553 28 days following vaccination in adolescents from 12 years to less than 18 years of age after a single immunisation. Study 2 (VLA1553-221) Randomised, observer-blinded, prospective, multicentre study to evaluate the safety, tolerability and immunogenicity of the adult dose and half dose of VLA1553 compared to control, to identify the optimal dose of VLA1553 in healthy subjects from 1 year to less than 12 years of age. Study 3 (VLA1553-322) Randomised, double-blinded, multicentre study to evaluate the immunogenicity and safety of the final paediatric dose VLA1553 28 days following vaccination in healthy subjects from 1 year to less than 12 years of age. Study 4 (VLA1553-222) Randomised, observer-blinded, prospective, multicentre study to evaluate either one or two dose levels of VLA1553 in male and female infants from birth to less than 1 year of age, in comparison to a control. Study

		5 (VLA1553-323) Randomised, double-blinded, prospective, multicentre, dose confirmation study to evaluate the final infant dose of VLA1553 in comparison to control, in subjects from birth to less than 1 year of age.
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:	30/04/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes