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 and grant a waiver

MHRA-100196-PIP01-21

Scope of the Application

Active Substance(s)

SARS-CoV-2 virus, beta-propiolactone inactivated

Condition(s)

Prevention of Coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

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 23/07/2021 13:46 BST an application for a Paediatric Investigation Plan

The procedure started on 23/08/2021 14:46 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-100196-PIP01-21

Of 31/01/2022 08:55 GMT

On the adopted decision for SARS-CoV-2 virus, beta-propiolactone inactivated (MHRA-100196-PIP01-21) 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 SARS-CoV-2 virus, beta-propiolactone inactivated, Suspension for injection , Intramuscular use .

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 Coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus disease 2019 (COVID-19)

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):

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 (VLA2001-301) Randomised, observer blinded, placebo controlled trial to evaluate the safety and immunogenicity of VLA2001 in adolescents from 12 years to less than 18 years of age (and adults) for the prevention of COVID-19 Study 2 (VLA2001-321) Randomised, double blinded, active controlled study to evaluate the dose and evaluate the safety, reactogenicity, and immunogenicity of different doses of VLA2001 Vaccine, in children from 2 years to less than 12 years of age for the prevention of COVID-19 Study 3 Randomised, double-blinded, active-controlled study to evaluate the safety, reactogenicity, and Immunogenicity of different doses of VLA2001 Vaccine, in children from birth to less than 2 years for the prevention of COVID-19 Study 4 An open label, uncontrolled study to evaluate the safety, reactogenicity, and immunogenicity of VLA2001 vaccine, in immunocompromised children from birth to less than 18 years for the prevention of COVID-19
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:	30/06/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes