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-100021-PIP01-21 -M01

Scope of the Application

Active Substance(s)

Recombinant SARS-CoV-2 spike (S)-protein virus-like particle

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

Medicago Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Medicago Inc. submitted to the licensing authority on 17/12/2021 17:14 GMT an application for a Modification

The procedure started on 05/01/2022 15:33 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 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-100021-PIP01-21 -M01

Of 11/02/2022 15:21 GMT

On the adopted decision for Recombinant SARS-CoV-2 spike (S)-protein virus-like particle (MHRA-100021-PIP01-21 -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

This decision applies to a Modification for Recombinant SARS-CoV-2 spike (S)-protein virus-like particle, Suspension for injection , Intramuscular use .

This decision is addressed to Medicago Inc., 1020 Route de l'Église, Suite 600, Quebec City, Canada, G1V 3V9

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:

Active immunisation for the prevention of Coronavirus disease 2019 (COVID-19), in individuals from birth to less than 18 years of age

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	1	Study 1 (PP-CoVLP-266) Developmental and Reproductive Toxicity (DART) Study on a Coronavirus-Like Particle (CoVLP) COVID-19 Vaccine Administered Intramuscularly in the Rat.
Clinical Studies	2	Study 2 (CP-PRO-CoVLP-023) A Phase 3 study with a multi-part design to evaluate the safety and effectiveness of Coronavirus-Like Particle COVID-19 Vaccine (CoVLP) in both healthy and immunocompromised paediatric populations, from 6 months to less than 18 years of age Study 3 A Phase 3 study with a multi-part design, to evaluate the safety and effectiveness of Coronavirus-Like Particle COVID-19 Vaccine (CoVLP) in both healthy and immunocompromised paediatric populations from birth to less than 6 months 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:	31/10/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes