MHRA
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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-100798-PIP01-22

Scope of the Application

Active Substance(s)

CX-000359 mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer / CX-000594 mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / CX- 000712 mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / CX-005128 mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / CX-005282 m-RNA encoding the gH protein in the CMV glycoprotein complex pentamer / CX-000667 mRNA encoding CMV gB (mRNA- 1647).

Condition(s)

Prevention of cytomegalovirus (CMV) infection

Pharmaceutical Form(s)

Powder for suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Moderna Biotech Spain, S.L

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Moderna Biotech Spain, S.L submitted to the licensing authority on 14/05/2024 00:26 BST an application for a Paediatric Investigation Plan

The procedure started on 05/06/2024 07:26 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 and grant a waiver

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-100798-PIP01-22

Of 09/09/2024 17:24 BST

On the adopted decision for CX-000359 mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer / CX- 000594 mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / CX- 000712 mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / CX-005128 mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / CX-005282 m-RNA encoding the gH protein in the CMV glycoprotein complex pentamer / CX-000667 mRNA encoding CMV gB (mRNA- 1647). (MHRA-100798-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 Paediatric Investigation Plan for CX-000359 mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer / CX- 000594 mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / CX- 000712 mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / CX-005128 mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / CX-005282 m-RNA encoding the gH protein in the CMV glycoprotein complex pentamer / CX-000667 mRNA encoding CMV gB (mRNA- 1647)., Powder for suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Moderna Biotech Spain, S.L, C/ Julián Camarillo nº 31, Madrid, SPAIN, 28037

ANNEX I

1. Waiver

1.1 Condition:

Prevention of cytomegalovirus (CMV) infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder for suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of cytomegalovirus (CMV) infection

2.2 Indication(s) targeted by the PIP:

Active immunisation to prevent CMV infection

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder 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 (mRNA 1647-P301) Randomised, observer-blind, placebo-controlled trial to evaluate efficacy, safety, and immunogenicity of mRNA-1647 cytomegalovirus vaccine in healthy female participants from 16 years to less than 18 years of age (and adults). Study 2 (mRNA 1647-P104) Open-label, dose-finding, observer-blind, placebo controlled, safety, and immunogenicity study of mRNA-1647 cytomegalovirus vaccine in healthy subjects from 9 years to less than 18 years of age (and adults). Study 3 (mRNA-1647-P303) Randomised, placebo-controlled study evaluating safety, reactogenicity, and immunogenicity

		of mRNA-1647 cytomegalovirus vaccine in healthy children and adolescent female participants from 9 years to less than 16 years of age. Study 4 (mRNA 1647-P308) Study to evaluate mRNA-1647 cytomegalovirus vaccine in immunocompromised children from 6 months to less than 18 years of age, part 1: Open label safety, immunogenicity, and dose finding, part 2: Safety, immunogenicity, and vaccine effectiveness.
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:	31/05/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes