EMA/210025/2023

European Medicines Agency decision

P/0195/2023

of 15 May 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345) (EMEA-003309-PIP01-22) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

European Medicines Agency decision

P/0195/2023

of 15 May 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345) (EMEA-003309-PIP01-22) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Moderna Biotech Spain, S.L. on 9 September 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345), dispersion for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345), dispersion for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345), dispersion for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Moderna Biotech Spain, S.L., Calle del Príncipe de Vergara 132 Plt 12, 28002 – Madrid, Spain.

EMA/PDCO/63973/2023
Amsterdam, 26 April 2023

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-003309-PIP01-22

Scope of the application

Active substance(s):

Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of lower respiratory tract illness caused by respiratory syncytial virus

Pharmaceutical form(s):

Dispersion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Moderna Biotech Spain, S.L.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Moderna Biotech Spain, S.L. submitted for agreement to the European Medicines Agency on 9 September 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 17 October 2022.

Supplementary information was provided by the applicant on 23 January 2023. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- dispersion for injection; intramuscular route;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

2.1.1. Indication(s) targeted by the PIP

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 weeks of age to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Dispersion for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (mRNA-1345-P101)** Randomised, observer-blind, placebo-controlled, dose escalation study to evaluate the safety, reactogenicity, and immunogenicity of single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (mRNA-1345) in respiratory syncytial virus (RSV) seropositive children from 12 months of age to less than 60 months of age. **Study 2 (mRNA-1365-P101)** Randomised, observer-blind, placebo controlled, age de-escalation study of the safety, tolerability, and immunogenicity of mRNA-1345 in children from 5 months of age to less than 24 months of age.

	Study 3 Randomised, observer-blind, placebo-controlled study of mRNA-1345 in children from 6 weeks of age to less than 7 months of age for regimen and dose selection, and safety, reactogenicity, and immunogenicity evaluation. Co-administration with routine childhood vaccines. **Study 4** Randomised, observer-blind, placebo-controlled study of mRNA-1345 in children from 6 weeks of age to less than 7 months of age for safety and efficacy evaluation for the prevention of RSV-associated lower respiratory tract illness (LRTI). Co-administration with routine childhood vaccines. **Study 5** Open-label study of safety, reactogenicity, and immunogenicity evaluation of mRNA-1345 in children from 7 months to less than 60 months of age **Study 6** Open-label study of safety, reactogenicity, and immunogenicity evaluation of mRNA-1345 in children from 5 years to less than 18 years of age with underlying conditions (Cohort A) and in immunocompromised children (Cohort B).
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2035
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.