EMA/482481/2024 Corr[1]

European Medicines Agency decision

P/0365/2024

of 25 October 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283), (EMEA-003426-PIP01-23-M02) 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.

[1] 30 October 2024

European Medicines Agency decision

P/0365/2024

of 25 October 2024

on the acceptance of a modification of an agreed paediatric investigation plan for mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283), (EMEA-003426-PIP01-23-M02) 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[2],

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[3],

Having regard to the European Medicines Agency's decision P/0007/2024 issued on 11 January 2024,

Having regard to the application submitted by Moderna Biotech Spain S.L. on 3 June 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 September 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral .

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283), dispersion for injection, intramuscular use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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

EMA/PDCO/283729/2024 Corr[1] Corr[2]
Amsterdam, 6 September 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-003426-PIP01-23-M02

Scope of the application

Active substance(s):

mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

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 22 of Regulation (EC) No 1901/2006 as amended, Moderna Biotech Spain S.L. submitted to the European Medicines Agency on 3 June 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0007/2024 issued on 11 January 2024.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

[1] 21 October 2024
[2] 30 October 2024

The procedure started on 8 July 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

The pharmaceutical form was amended.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Active immunisation to prevent COVID-19 caused by SARS-CoV-2

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

From birth 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-1283-P301)** Randomised, observer-blind, active-controlled, multi-centre, 2-stage, group sequential study to investigate the safety, immunogenicity, efficacy, and reactogenicity of mRNA-1283.222 in part 1 and mRNA-1283.815 in Part 3 in participants aged 12 years and older for the prevention of COVID-19 (and adults). **Study 2 (mRNA-1283-P302)** Dose-ranging study (part 1) and randomised, observer-blind, active-controlled safety and immunogenicity study (part 2) in participants aged 6 months to less than 12 years of age with and without prior history of vaccination. Part 2A will enrol participants aged from 6 months to less than 5 years of age who have been previously vaccinated and participants from 5 to less than 12 years of age regardless of prior vaccination to receive a single dose vaccination. Part 2B will enrol participants from 6 months to less than 5 years of age who have not been previously vaccinated to receive a two-dose vaccination regimen.

	Study 3 (mRNA-1283-Pxxx) Dose-finding (cohort 1) and randomized, active-controlled, observer-blind, study (cohort 2) to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1283 SARS-CoV-2 vaccine administered as 2 doses 6-8 weeks apart in infants from birth to less than 6 months of age.
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 June 2034
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.