Clinical trial results:
A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Adolescents 12 to <18 Years of Age

Summary

EudraCT number	2023-000382-14
Trial protocol	Outside EU/EEA
Global end of trial date	12 July 2024

Results information

Result version number	v1
This version publication date	26 January 2025
First version publication date	26 January 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P203

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04649151
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, MA, United States, 02142
Public contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., +1 877-777-7187, clinicaltrials@modernatx.com
Scientific contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., +1 877-777-7187, clinicaltrials@modernatx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002893-PIP01-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 June 2024
Global end of trial reached?	Yes
Global end of trial date	12 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study was designed to primarily evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 vaccine administered as primary series and a booster dose (BD) to an adolescent population. The study also evaluated the safety and immunogenicity of an mRNA-1273.222 vaccine against the SARS-CoV- 2 omicron variant.

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, and Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and other applicable laws and regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 3994
Country: Number of subjects enrolled	Dominican Republic: 334
Worldwide total number of subjects	4328
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	4328
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included Part 1A as the Blinded Phase with participants remaining blinded until the initiation of Part 1B (open-label cross-over phase), and Parts 1C-1, 1C-2, 2, and 3 as open-label. A comparison to the mRNA-1273-P301 (P301) (NCT04470427) study's efficacy data was performed on a subgroup of P301 study participants aged 18-25 (N=296).

Period 1

Period 1 title	Parts 1, 2, and 3
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Monitor

Blinding implementation details:

Part 1A was observer-blind. Participants remained blinded until the initiation of Part 1B (open-label cross-over phase). Parts 1C-1, 1C-2, 2, and 3 were open-label.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1A: mRNA-1273 100 µg

Arm description:

Participants received 2 doses of 100 micrograms (µg) mRNA-1273 by intramuscular (IM) injection (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1A: Placebo

Arm description:

Participants received 2 doses of placebo matched to mRNA-1273 100 µg by IM injection (Day 1 and Day 29).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1273 was administered per schedule specified in the arm description.

Arm title	Part 1C-2: mRNA-1273 50 µg BD

Arm description:

Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under emergency use authorization (EUA), received a single BD of 50 µg mRNA-1273 IM injection on BD Day 1.

Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2: mRNA-1273 50 µg

Arm description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 3: mRNA-1273.222 50 µg

Arm description:

Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1). Some participants may have received a second dose of mRNA-1273.222 50 µg at approximately 6 months after the first dose (Day 181).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.222 was administered per dose and schedule specified in the arm description.

Number of subjects in period 1	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo	Part 1C-2: mRNA-1273 50 µg BD
Started	2490	1243	155
Part 1: 1st Injection	2486	1240	0 [1]
Part 2: 1st Injection	0 [2]	0 [3]	0 [4]
Part 1: 2nd Injection	2480	1222	0 [5]
Part 2: 2nd Injection	0 [6]	0 [7]	0 [8]
Part 1C-2: BD	0 [9]	0 [10]	155
Part 3: 1 Dose	0 [11]	0 [12]	0 [13]
Part 3: 2 Doses	0 [14]	0 [15]	0 [16]
Safety Analysis Set	2486	1240	155
Solicited Safety Set	2485	1240	125 [17]
Per-Protocol (PP) Immunogenicity Subset	340 [18]	0 [19]	136 [20]

PP Set for Efficacy	2142 [21]	1044	0 [22]
Part 2 BD	0 [23]	0 [24]	0 [25]
PP Immunogenicity SARS-CoV-2 Positive	0 [26]	0 [27]	0 [28]
Completed	2246	279	143
Not completed	244	964	12
Physician decision	2	-	-
Consent withdrawn by subject	112	88	2
Protocol Deviation	2	2	-
Adverse event, non-fatal	1	-	-
Death	-	-	-
Pregnancy	-	-	-
Other than specified	21	229	-
Received another COVID-19 vaccine under EUA	39	630	-
Lost to follow-up	67	15	10

Number of subjects in period 1	Part 2: mRNA-1273 50 µg	Part 3: mRNA-1273.222 50 µg
Started	52	388
Part 1: 1st Injection	0 [29]	0 [30]
Part 2: 1st Injection	52	0 [31]
Part 1: 2nd Injection	0 [32]	0 [33]
Part 2: 2nd Injection	50	0 [34]
Part 1C-2: BD	0 [35]	0 [36]
Part 3: 1 Dose	0 [37]	388
Part 3: 2 Doses	0 [38]	335 [39]
Safety Analysis Set	52	388
Solicited Safety Set	52	387
Per-Protocol (PP) Immunogenicity Subset	46	373
PP Set for Efficacy	0 [40]	0 [41]
Part 2 BD	19 [42]	0 [43]
PP Immunogenicity SARS-CoV-2 Positive	44	372
Completed	41	358
Not completed	11	30
Physician decision	1	1
Consent withdrawn by subject	7	15
Protocol Deviation	-	-
Adverse event, non-fatal	-	-
Death	-	1
Pregnancy	-	3
Other than specified	-	4

Received another COVID-19 vaccine under EUA	-	-
Lost to follow-up	3	6

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[18] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[19] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[20] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[21] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[22] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[23] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[24] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[25] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[26] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[27] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[28] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[29] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: Value indicates the number of applicable participants for the milestone and dose group.

[30] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[31] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[32] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[33] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[34] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[35] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[36] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[37] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[38] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[39] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[40] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[41] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[42] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[43] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

Period 2

Period 2 title	Part 1C-1 BD
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Part 1C-1: mRNA-1273 50 µg BD

Arm description:

Participants received mRNA-1273 100 µg in blinded or cross-over phase (Parts 1A or 1B) and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 1 C-1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Number of subjects in period 2[44]	Part 1C-1: mRNA-1273 50 µg BD
Started	1408
Safety Set	1408
Solicited Safety Set	1351
PPIS	331 [45]
PP Immunogenicity SARS-CoV-2 Negative	267 [46]
Completed	1136
Not completed	272
Physician decision	3
Consent withdrawn by subject	123
Protocol Deviation	2
Other than specified	4
Received another COVID-19 vaccine under EUA	17
Lost to follow-up	123

Notes:

[44] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants who started in Part 1 received BD in Part 1C-1.

[45] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

[46] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Value indicates the number of applicable participants for the milestone and dose group.

Period 3

Period 3 title	Part 1B Crossover Phase
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Part 1 B: mRNA-1273 100 µg

Arm description:

Participants previously received 2 doses of placebo in the blinded phase and then received crossover vaccination with 100 µg of mRNA-1273.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Number of subjects in period 3[47]	Part 1 B: mRNA-1273 100 µg
Started	96
Received First Injection on Day 1	96
Received Second Injection on Day 29	93
Safety Set	96
Completed	93
Not completed	3
Adverse event, non-fatal	1
Other than specified	1
Lost to follow-up	1

Notes:

[47] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants who received placebo in Part 1 crossed over to Part 1B

Baseline characteristics

Reporting groups	
Reporting group title	Part 1A: mRNA-1273 100 µg
Reporting group description:	
Participants received 2 doses of 100 micrograms (µg) mRNA-1273 by intramuscular (IM) injection (Day 1 and Day 29).	
Reporting group title	Part 1A: Placebo
Reporting group description:	
Participants received 2 doses of placebo matched to mRNA-1273 100 µg by IM injection (Day 1 and Day 29).	
Reporting group title	Part 1C-2: mRNA-1273 50 µg BD
Reporting group description:	
Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under emergency use authorization (EUA), received a single BD of 50 µg mRNA-1273 IM injection on BD Day 1.	
Reporting group title	Part 2: mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).	
Reporting group title	Part 3: mRNA-1273.222 50 µg
Reporting group description:	
Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1). Some participants may have received a second dose of mRNA-1273.222 50 µg at approximately 6 months after the first dose (Day 181).	

Reporting group values	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo	Part 1C-2: mRNA-1273 50 µg BD
Number of subjects	2490	1243	155
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	2490	1243	155
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Subjects			
Female	1206	607	78
Male	1284	636	77

Reporting group values	Part 2: mRNA-1273 50 µg	Part 3: mRNA-1273.222 50 µg	Total
Number of subjects	52	388	4328
Age Categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	52	388	4328
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Subjects			
Female	26	185	2102
Male	26	203	2226

Subject analysis sets

Subject analysis set title	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject analysis set type	Per protocol
Subject analysis set description: Participants (young adults; 18-25 years of age) received 100 µg mRNA-1273 on a 2 injection schedule in Study mRNA-1273-P301 (P301).	
Subject analysis set title	Part 2: mRNA-1273 50 µg First Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received 1 dose of 50 µg mRNA-1273 by IM injection (Day 1).	
Subject analysis set title	Part 2: mRNA-1273 50 µg Second Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received 2nd dose of 50 µg mRNA-1273 by IM injection (Day 29).	
Subject analysis set title	Part 2: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received open-label mRNA-1273 50 µg in Part 2 and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 2.	
Subject analysis set title	Part 3: mRNA-1273.222 50 µg 1 Dose
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1).	
Subject analysis set title	Part 1A: mRNA-1273 100 µg
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received at least 1 dose of the 2-dose series of 100 µg mRNA-1273 by IM injection (Day 1 and Day 29).	
Subject analysis set title	Part 1A: Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received at least 1 dose of the 2-dose series of placebo matched to mRNA-1273 100 µg by IM injection (Day 1 and Day 29).	
Subject analysis set title	Part 1B: mRNA-1273 100 µg
Subject analysis set type	Safety analysis
Subject analysis set description: Participants previously received 2 doses of placebo in the blinded phase and then received crossover vaccination with 100 µg of mRNA-1273.	

Subject analysis set title	Part 1C-1: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received mRNA-1273 100 µg in blinded or cross-over phase (Parts 1A or 1B) and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 1 C-1.

Subject analysis set title	Part 1C-2: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under EUA, received a single BD of 50 µg mRNA-1273 IM injection on BD Day 1

Subject analysis set title	Part 2: mRNA-1273 50 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received at least 1 dose of the 2-dose series of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Reporting group values	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	Part 2: mRNA-1273 50 µg First Injection	Part 2: mRNA-1273 50 µg Second Injection
Number of subjects	296	52	50
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	296		
From 65-84 years	0		
85 years and over	0		
Gender Categorical Units: Subjects			
Female	153		
Male	143		

Reporting group values	Part 2: mRNA-1273 50 µg BD	Part 3: mRNA-1273.222 50 µg 1 Dose	Part 1A: mRNA-1273 100 µg
Number of subjects	19	388	2486
Age Categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Gender Categorical Units: Subjects			
Female Male			

Reporting group values	Part 1A: Placebo	Part 1B: mRNA-1273 100 µg	Part 1C-1: mRNA-1273 50 µg BD
Number of subjects	1240	96	1408
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender Categorical Units: Subjects			
Female Male			

Reporting group values	Part 1C-2: mRNA-1273 50 µg BD	Part 2: mRNA-1273 50 µg	
Number of subjects	155	52	
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender Categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	Part 1A: mRNA-1273 100 µg
Reporting group description:	
Participants received 2 doses of 100 micrograms (µg) mRNA-1273 by intramuscular (IM) injection (Day 1 and Day 29).	
Reporting group title	Part 1A: Placebo
Reporting group description:	
Participants received 2 doses of placebo matched to mRNA-1273 100 µg by IM injection (Day 1 and Day 29).	
Reporting group title	Part 1C-2: mRNA-1273 50 µg BD
Reporting group description:	
Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under emergency use authorization (EUA), received a single BD of 50 µg mRNA-1273 IM injection on BD Day 1.	
Reporting group title	Part 2: mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).	
Reporting group title	Part 3: mRNA-1273.222 50 µg
Reporting group description:	
Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1). Some participants may have received a second dose of mRNA-1273.222 50 µg at approximately 6 months after the first dose (Day 181).	
Reporting group title	Part 1C-1: mRNA-1273 50 µg BD
Reporting group description:	
Participants received mRNA-1273 100 µg in blinded or cross-over phase (Parts 1A or 1B) and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 1 C-1.	
Reporting group title	Part 1 B: mRNA-1273 100 µg
Reporting group description:	
Participants previously received 2 doses of placebo in the blinded phase and then received crossover vaccination with 100 µg of mRNA-1273.	
Subject analysis set title	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants (young adults; 18-25 years of age) received 100 µg mRNA-1273 on a 2 injection schedule in Study mRNA-1273-P301 (P301).	
Subject analysis set title	Part 2: mRNA-1273 50 µg First Injection
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 dose of 50 µg mRNA-1273 by IM injection (Day 1).	
Subject analysis set title	Part 2: mRNA-1273 50 µg Second Injection
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2nd dose of 50 µg mRNA-1273 by IM injection (Day 29).	
Subject analysis set title	Part 2: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received open-label mRNA-1273 50 µg in Part 2 and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 2.	
Subject analysis set title	Part 3: mRNA-1273.222 50 µg 1 Dose
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1).	

Subject analysis set title	Part 1A: mRNA-1273 100 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received at least 1 dose of the 2-dose series of 100 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Subject analysis set title	Part 1A: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received at least 1 dose of the 2-dose series of placebo matched to mRNA-1273 100 µg by IM injection (Day 1 and Day 29).

Subject analysis set title	Part 1B: mRNA-1273 100 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants previously received 2 doses of placebo in the blinded phase and then received crossover vaccination with 100 µg of mRNA-1273.

Subject analysis set title	Part 1C-1: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received mRNA-1273 100 µg in blinded or cross-over phase (Parts 1A or 1B) and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 1 C-1.

Subject analysis set title	Part 1C-2: mRNA-1273 50 µg BD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under EUA, received a single BD of 50 µg mRNA-1273 IM injection on BD Day 1

Subject analysis set title	Part 2: mRNA-1273 50 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received at least 1 dose of the 2-dose series of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Primary: Number of Participants With Solicited Local and Systemic Adverse Reactions (ARs)

End point title	Number of Participants With Solicited Local and Systemic Adverse Reactions (ARs)[1][2]

End point description:

Solicited ARs (local and systemic) were collected in an electronic diary (eDiary). Local ARs included injection site pain, injection site erythema (redness), injection site swelling/induration (hardness), and axillary (underarm) swelling or tenderness ipsilateral to the side of injection. Systemic ARs included fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Solicited ARs considered causally related to injection were graded 1-4 (per Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials); lower score indicated lower severity, and higher score indicated greater severity. Solicited Safety Set included participants who received at least 1 dose of study drug and contributed any solicited AR data. Investigator reviewed if the solicited AR was recorded as an adverse event (AE). A Summary of serious AEs (SAEs) and nonserious AEs ("Other"), regardless of causality, is located in the AE section.

End point type	Primary

End point timeframe:

7 days post-vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1C-1: mRNA-1273 50 µg BD	Part 1A: Placebo	Part 1C-2: mRNA-1273 50 µg BD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2485	1351	1240	125
Units: participants				
Grade 1	586	627	585	42
Grade 2	1250	501	293	48
Grade 3	627	150	59	9
Grade 4	3	0	1	0
Any Solicited AR	2466	1278	938	99

End point values	Part 2: mRNA-1273 50 µg First Injection	Part 2: mRNA-1273 50 µg Second Injection	Part 2: mRNA-1273 50 µg BD	Part 3: mRNA-1273.222 50 µg 1 Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	46	19	387
Units: participants				
Grade 1	25	18	7	145
Grade 2	16	9	0	62
Grade 3	1	3	1	25
Grade 4	0	0	0	1
Any Solicited AR	42	30	8	233

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited AEs

End point title	Number of Participants With Unsolicited AEs[3][4]

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Any abnormal laboratory test result or other safety assessment, including one that worsened from baseline and was considered clinically significant by the Investigator was recorded as an AE.
Non-serious SARs persisting beyond 7 days, leading to discontinuation, or medically attended were defined as AEs in Part 1/2 but not in Part 3. COVID-19/SARS-CoV-2 infections were AEs in Part1/2 but were considered clinical events for efficacy in Part 3 and not AEs.
A Summary of SAEs and nonserious AEs ("Other"), regardless of causality, is located in the AE section.
Safety Set: participants who received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Up to 28 days post-vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1C-1: mRNA-1273 50 µg BD	Part 1A: Placebo	Part 1C-2: mRNA-1273 50 µg BD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2486	1405	1240	155
Units: participants	582	209	237	19

End point values	Part 2: mRNA-1273 50 µg	Part 2: mRNA-1273 50 µg BD	Part 3: mRNA-1273.222 50 µg 1 Dose	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	52	19	388	
Units: participants	10	2	52	

Statistical analyses

No statistical analyses for this end point

Primary: Part 1A Seroresponse Rate (SRR) for Serum Pseudovirus nAb ID50 in Study P203 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 1A Seroresponse Rate (SRR) for Serum Pseudovirus nAb ID50 in Study P203 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301[5]

End point description:

Percentage of participants with seroresponse for pseudovirus nAb ID50 measured using PsVNA assay are reported. Seroresponse was defined as a change from below the LLOQ to equal above 4*LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 in P301 Part A and who were baseline SARS-CoV-2 negative in P301 Part A.
PPIS: all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data.

End point type	Primary

End point timeframe:

Day 57 Study P203/Day 57 Study P301

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	340	295		
Units: percentage of participants				
number (confidence interval 95%)	98.8 (97.0 to 99.7)	99.0 (97.1 to 99.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: SRR difference of P203 vs P301	
Comparison groups	Part 1A: mRNA-1273 100 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	635
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	1.9

Primary: Part 1A Geometric Mean Value of Serum Pseudovirus Neutralizing Antibody (nAb) ID50 Titers From Study P203 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 1A Geometric Mean Value of Serum Pseudovirus Neutralizing Antibody (nAb) ID50 Titers From Study P203 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301[6]

End point description:

Pseudovirus nAb ID50 titers were measured using pseudovirus neutralization assay (PsVNA) assay. Antibody values reported as below the lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ. Values greater than the upper limit of quantification (ULOQ) were replaced by the ULOQ if actual values were not available (LLOQ: 18.5, ULOQ: 45118). Antibody levels were analyzed using an analysis of covariance (ANCOVA) model with the group variable (adolescents in P203 and young adults in P301) as fixed effect. The geometric least squares means are presented. PP Immunogenicity Set (PPIS): all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data.

End point type	Primary

End point timeframe:

Day 57 Study P203/Day 57 Study P301

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	340	295		
Units: titer				
geometric mean (confidence interval 95%)	1401.670 (1276.218 to 1539.453)	1299.855 (1175.380 to 1437.511)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Geometric mean ratio (GMR) of P203 vs P301	
Comparison groups	Part 1A: mRNA-1273 100 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	635
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	1.078
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.237

Primary: Part 1C-1 Geometric Mean Concentration (GMC) of Serum Pseudovirus nAb Against the Original Strain After the BD in Study P203 at BD Day 29 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 1C-1 Geometric Mean Concentration (GMC) of Serum Pseudovirus nAb Against the Original Strain After the BD in Study P203 at BD Day 29 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point description:

Pseudovirus nAb were measured using PsVNA assay. Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available (LLOQ: 10, ULOQ: 281600). PPIS-Neg: All participants who received mRNA-1273 in the Blinded Phase per schedule, received BD, had a negative SARS-CoV-2 status at baseline (pre-Dose 1 of the Blinded Phase), had BD-Day 1 and BD-Day 29 Ab assessment for the analysis endpoint, had no major protocol deviations that impacted key or critical data, and were pre-booster SARS-CoV-2 negative, defined as no virologic or serologic evidence of SARSCoV-2 infection on or before BD-Day 1 (pre-booster). P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 in P301 Part A and who were baseline SARS-CoV-2 negative in P301 Part A. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

BD Day 29 Study P203/Day 57 Study P301

End point values	Part 1C-1: mRNA-1273 50 µg BD	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	264	294		
Units: arbitrary units (AU)/mL				
geometric mean (confidence interval 95%)	7102.0 (6553.2 to 7696.8)	1400.4 (1272.7 to 1541.0)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
GMC Comparison of BD-Day 29 P203 vs Day 57 P301	
Comparison groups	Part 1C-1: mRNA-1273 50 µg BD v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	558
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	5.071
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.477
upper limit	5.745

Primary: Part 3 GMC of nAb post Dose 1 mRNA 1273.222 Against Omicron BA.4/BA.5 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 3 GMC of nAb post Dose 1 mRNA 1273.222 Against Omicron BA.4/BA.5 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301[7]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available (LLOQ: 103 AU/mL, ULOQ: 28571 AU/mL). ANCOVA model with the group variable (adolescents in P203 and young adults in P301) as fixed effect. The geometric least squares means are presented. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA 1273 and were baseline SARS-CoV-2 negative. PPIS-Baseline SARS-CoV-2 Positive (PPIS-POS): all participants who received Dose 1 of mRNA-1273.222, had both Baseline (pre Dose 1) and Day 29 antibody assessment, had no major protocol deviations that impacted key or critical data, had not received off-study COVID-19 vaccination prior to Day 29, and were SARS-CoV-2 positive (serologic and/or virologic evidence of prior SARS-CoV-2 infection) at baseline. "Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 29 Study P203/Day 57 Study P301

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 3: mRNA-1273.222 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	372	294		
Units: AU/mL				
geometric mean (confidence interval 95%)	2727.8 (2558.7 to 2908.1)	56.6 (52.7 to 60.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

GMR of P203 vs P301

Comparison groups	Part 3: mRNA-1273.222 50 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	666
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	GMR
Point estimate	48.191
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.765
upper limit	53.065

Primary: Part 2 GMC of the Pseudovirus nAb Against Ancestral Strain at Day 57

End point title	Part 2 GMC of the Pseudovirus nAb Against Ancestral Strain at Day 57[8][9]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5 * LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available (LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). PPIS: all randomized participants who received at least 1 dose of the planned study drug, had Ab assessment for the analysis endpoint, and had no major protocol deviations that could impact key or critical data.

End point type	Primary

End point timeframe:

Day 57

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Part 2, due to the smaller number of participants enrolled, hypothesis testing was not conducted. Descriptive analysis included.
[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Part 2, due to the smaller number of participants enrolled, hypothesis testing was not conducted. Descriptive analysis included.

End point values	Part 2: mRNA-1273 50 µg			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: AU/mL				
geometric mean (confidence interval 95%)	7351.5 (5621.7 to 9613.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Part 1C-1 SRR of Serum Pseudovirus nAb Against the Original Strain After the BD in Study P203 at BD Day 29 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 1C-1 SRR of Serum Pseudovirus nAb Against the Original Strain After the BD in Study P203 at BD Day 29 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to pre-Dose 1 (baseline) at a participant level was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold-rise if baseline was equal to or above LLOQ. PPIS-Neg: all participants who received mRNA-1273 in the Blinded Phase per schedule, received BD, had a negative SARS-CoV-2 status at baseline (pre-Dose 1 of the Blinded Phase), had BD-Day 1 and BD-Day 29 Ab assessment, had no major protocol deviations that impacted key or critical data, and were pre-booster SARS-CoV-2 negative, defined as no virologic or serologic evidence of SARSCoV-2 infection on or before BD-Day 1. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 in P301 Part A and who were baseline SARS-CoV-2 negative in P301 Part A.

End point type	Primary

End point timeframe:

BD Day 29 Study P203/Day 57 Study P301

End point values	Part 1C-1: mRNA-1273 50 µg BD	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	264	294		
Units: percentage of participants				
number (confidence interval 95%)	100.0 (98.6 to	99.3 (97.6 to		

100.0)	99.9)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
SRR difference of P203 BD-Day 29 vs P301 Day 57	
Comparison groups	Part 1C-1: mRNA-1273 50 µg BD v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	558
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	SRR Difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	2.4

Primary: Part 1C-2 GMC of Post-booster Pseudovirus nAb Against Ancestral Strain at BD Day 29

End point title	Part 1C-2 GMC of Post-booster Pseudovirus nAb Against Ancestral Strain at BD Day 29[10][11]
End point description:	
Antibody values reported as below the LLOQ were replaced by 0.5 * LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available (LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). PPIS: all randomized participants who received BD in Part 1C-2, had BD-Day 29 Ab assessment for the analysis endpoint, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.	
End point type	Primary
End point timeframe:	
BD Day 29	

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Part 1C-2 enrollment discontinued before planned number of participants were met for prespecified statistical analysis to be conducted.
[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Part 1C-2 enrollment discontinued before planned number of participants were met for prespecified statistical analysis to be conducted.

End point values	Part 1C-2: mRNA-1273 50 µg BD			
Subject group type	Reporting group			
Number of subjects analysed	134			
Units: AU/mL				
geometric mean (confidence interval 95%)	9433.4 (8496.8 to 10473.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Part 3 GMC of nAb post Dose 1 mRNA 1273.222 Against SARS-CoV-2 Ancestral Strain Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301

End point title	Part 3 GMC of nAb post Dose 1 mRNA 1273.222 Against SARS-CoV-2 Ancestral Strain Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in Study P301[12]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available (LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). ANCOVA model with the group variable (adolescents in P203 and young adults in P301) as fixed effect. The geometric least squares means are presented. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 and were baseline SARS-CoV-2 negative. PPIS-POS: all participants who received Dose 1 of mRNA-1273.222, had both Baseline (pre Dose 1) and Day 29 antibody assessment, had no major protocol deviations that impacted key or critical data, had not received off-study COVID-19 vaccination prior to Day 29, and were SARS-CoV-2 positive (serologic and/or virologic evidence of prior SARS-CoV-2 infection) at baseline. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 29 Study P203/Day 57 Study P301

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 3: mRNA-1273.222 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	371	295		
Units: AU/mL				
geometric mean (confidence interval 95%)	7603.9 (7004.6 to 8254.6)	1692.3 (1543.4 to 1855.5)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: GMR of P203 vs P301	
Comparison groups	Part 3: mRNA-1273.222 50 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	666
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	4.493
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.972
upper limit	5.083

Primary: Part 2 SRR of Pseudovirus nAb Against Ancestral Strain

End point title	Part 2 SRR of Pseudovirus nAb Against Ancestral Strain[13][14]

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to pre-Dose 1 (baseline) at a participant level was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold-rise if baseline was equal to or above the LLOQ. PPIS: all randomized participants who received at least 1 dose of the planned study drug, had Ab assessment for the analysis endpoint, and had no major protocol deviations that could impact key or critical data.

End point type	Primary

End point timeframe:

Day 57

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Part 2, due to the smaller number of participants enrolled, hypothesis testing was not conducted. Descriptive analysis included.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Part 2, due to the smaller number of participants enrolled, hypothesis testing was not conducted. Descriptive analysis included.

End point values	Part 2: mRNA-1273 50 µg			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: percentage of participants				
number (confidence interval 95%)	91.3 (79.2 to 97.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With SAEs, AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs leading to Study Discontinuation

End point title	Number of Participants With SAEs, AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs leading to Study Discontinuation[15][16]

End point description:

SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability/permanent damage, was a congenital anomaly/birth defect, or was an important medical event. AESIs included thrombocytopenia, new onset of or worsening of the protocol specified neurologic diseases, anaphylaxis, and myocarditis/pericarditis. MAAE was an AE that led to an unscheduled visit to a healthcare practitioner, included visits to a study site for unscheduled assessments (for example, abnormal laboratory follow-up, and visits to healthcare practitioners external to the study site [for example, urgent care, primary care physician]). Number of participants with SAEs, AESIs, MAAEs, and AEs leading to study discontinuation up to end of study (EOS) are reported in this endpoint. Participants who received at least 1 dose of mRNA-1273 were included in the analysis.

End point type	Primary

End point timeframe:

Day 1 up to Day 751 (end of study [EOS])

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1C-1: mRNA-1273 50 µg BD	Part 1C-2: mRNA-1273 50 µg BD	Part 2: mRNA-1273 50 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2486	1408	155	52
Units: participants				
SAEs	21	9	3	0
AESIs	17	9	1	0
MAAEs	1040	541	45	12
AEs Leading to Study Discontinuation	0	0	0	0

End point values	Part 3: mRNA-1273.222 50 µg	Part 2: mRNA-1273 50 µg BD	Part 1B: mRNA-1273 100 µg	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	388	19	96	
Units: participants				
SAEs	16	0	2	
AESIs	3	0	0	
MAAEs	183	7	31	
AEs Leading to Study Discontinuation	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1A Number of Participants with a SARS-CoV-2 Infection (Symptomatic or Asymptomatic)

End point title	Part 1A Number of Participants with a SARS-CoV-2 Infection (Symptomatic or Asymptomatic)[17]

End point description:

SARS-CoV-2 infection was defined in participants with negative SARS-CoV-2 status at baseline: bAb level against SARS-CoV-2 nucleocapsid protein negative at Day 1, that became positive postbaseline; or positive postbaseline. PP Set for Efficacy: all randomized participants who received planned doses of study drug, had no immunologic or virologic evidence of prior COVID-19, and had no major protocol deviations that impact key or critical efficacy data.

End point type	Secondary

End point timeframe:

Day 43 (14 days after second injection) up to a median follow up of 2.5 months after second injection

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2142	1044		
Units: participants	22	25		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Vaccine efficacy (VE, percent), was defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo).

Comparison groups	Part 1A: mRNA-1273 100 µg v Part 1A: Placebo
Number of subjects included in analysis	3186
Analysis specification	Pre-specified
Analysis type	other[18]
Method	VE
Parameter estimate	VE
Point estimate	60.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	26.6
upper limit	78.6

Notes:

[18] - The 95% confidence interval (CI) of the ratio was calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Secondary: Part 1A Number of Participants with a First Occurrence of Symptomatic COVID-19

End point title	Part 1A Number of Participants with a First Occurrence of Symptomatic COVID-19[19]

End point description:

COVID-19 was defined as symptomatic disease based on the following criteria: participants experienced at least 2 of the following systemic symptoms: fever (≥ 38ºC/≥ 100.4ºF), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or experienced at least 1 of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and had at least 1 NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2. PP Set for Efficacy: all randomized participants who received planned doses of study drug, had no immunologic or virologic evidence of prior COVID-19, and had no major protocol deviations that impact key or critical efficacy data.

End point type	Secondary

End point timeframe:

Day 43 (14 days after second injection) up to 2.5 months after second injection

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2142	1044		
Units: participants	0	6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

VE (percent), was defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo).

Comparison groups	Part 1A: mRNA-1273 100 µg v Part 1A: Placebo
Number of subjects included in analysis	3186
Analysis specification	Pre-specified
Analysis type	other[20]
Method	VE
Parameter estimate	VE
Point estimate	100

Confidence interval	
level	95 %
sides	2-sided
lower limit	61.2
upper limit	9999

Notes:

[20] - The 95% CI of the ratio was calculated using the exact method conditional upon the total number of cases, adjusting for person-years. 9999= not estimable (NE, not reached).

Secondary: Part 1A Number of Participants With Asymptomatic SARS-CoV-2 Infection

End point title	Part 1A Number of Participants With Asymptomatic SARS-CoV-2 Infection[21]

End point description:

Asymptomatic SARS-CoV-2 infection was defined as absence of symptoms and a positive RT-PCR or serology test (bAb levels against SARS-CoV-2 nucleocapsid protein) post dosing in participants who did not have an infection at baseline or pre-Dose 1. PP Set for Efficacy: all randomized participants who received planned doses of study drug, had no immunologic or virologic evidence of prior COVID-19, and had no major protocol deviations that impact key or critical efficacy data.

End point type	Secondary

End point timeframe:

Day 43 (14 days after second injection) up to a median follow up of 2.5 months after second injection

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2142	1044		
Units: participants	20	16		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

VE (percent), was defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo).

Comparison groups	Part 1A: mRNA-1273 100 µg v Part 1A: Placebo
Number of subjects included in analysis	3186
Analysis specification	Pre-specified
Analysis type	other[22]
Method	VE
Parameter estimate	VE
Point estimate	43.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.5
upper limit	72.2

Notes:

[22] - The 95% CI of the ratio was calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Secondary: Part 1C-1 SRR of the Post-booster Serum bAb Against Variants of Interest (B.1.1.7, B.1.351, B.1.617.2, and P.1) as Measured by MSD

End point title	Part 1C-1 SRR of the Post-booster Serum bAb Against Variants of Interest (B.1.1.7, B.1.351, B.1.617.2, and P.1) as Measured by MSD

End point description:

Seroresponse from baseline (pre-Dose 1) at a participant level was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold-rise if baseline (pre-Dose 1 is equal to or above the LLOQ. PPIS: all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

BD Day 29

End point values	Part 1C-1: mRNA-1273 50 µg BD			
Subject group type	Reporting group			
Number of subjects analysed	324			
Units: Percentage of participants				
number (confidence interval 95%)				
B.1.1.7	100.0 (98.9 to 100.0)			
B.1.351	100.0 (98.9 to 100.0)			
B.1.617.2	100.0 (98.9 to 100.0)			
P.1	100.0 (98.9 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1A Number of Participants with Secondary Case Definition of COVID-19 (Center for Disease Control and Prevention [CDC] Case Definition)

End point title	Part 1A Number of Participants with Secondary Case Definition of COVID-19 (Center for Disease Control and Prevention [CDC] Case Definition)[23]

End point description:

Secondary case definition of COVID-19 was defined by the following criteria: 1 systemic or respiratory symptoms: fever (temperature > 38ºC/≥ 100.4ºF), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches, or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea, or vomiting or diarrhea, and at least one positive test for SARS-CoV-2. PP Set for Efficacy: all randomized participants who received planned doses of study drug, had no immunologic or virologic evidence of prior COVID-19, and had no major protocol deviations that impact key or critical efficacy data.

End point type	Secondary

End point timeframe:

Day 43 (14 days after second injection) up to a median follow up of 2.5 months after second injection

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg	Part 1A: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2142	1044		
Units: participants	2	9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

VE (percent), was defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo).

Comparison groups	Part 1A: mRNA-1273 100 µg v Part 1A: Placebo
Number of subjects included in analysis	3186
Analysis specification	Pre-specified
Analysis type	other[24]
Method	VE
Parameter estimate	VE
Point estimate	89.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	51
upper limit	98.9

Notes:

[24] - The 95% CI of the ratio was calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Secondary: Part 3 Pseudovirus nAb SRR of post Dose 1 of mRNA-1273.222 Against Ancestral Strain Compared to Study P301

End point title	Part 3 Pseudovirus nAb SRR of post Dose 1 of mRNA-1273.222 Against Ancestral Strain Compared to Study P301[25]

End point description:

Seroresponse from pre Dose 1 Baseline at a participant level was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold rise if Baseline was equal to or above the LLOQ. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 in P301 Part A and who were baseline SARS-CoV-2 negative in P301 Part A. PPIS-POS: all participants who received Dose 1 of mRNA-1273.222, had both Baseline (pre Dose 1) and Day 29 antibody assessment, had no major protocol deviations that impacted key or critical data, had not received off-study COVID-19 vaccination prior to Day 29 Visit, and who were SARS-CoV-2 positive (serologic and/or virologic evidence of prior SARS-CoV-2 infection) at baseline. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 29 P203/Day 57 P301

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 3: mRNA-1273.222 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	370	295		
Units: percentage of participants				
number (confidence interval 95%)	94.9 (92.1 to 96.9)	99.3 (97.6 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1C-1 GMC of Post-booster Pseudovirus nAb Against Variant Strain (B.1.1.529)

End point title	Part 1C-1 GMC of Post-booster Pseudovirus nAb Against Variant Strain (B.1.1.529)

End point description:

Post-booster Pseudovirus nAb against B.1.1.529 (LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL). Antibody values reported as below the LLOQ were replaced by 0.5 * LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available. PP IS: all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

BD Day 29

End point values	Part 1C-1: mRNA-1273 50 µg BD			
Subject group type	Reporting group			
Number of subjects analysed	331			
Units: AU/mL				
geometric mean (confidence interval 95%)	943.4 (853.5 to 1042.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3 SRR of Serum Pseudovirus nAb Post Dose 1 of mRNA-1273.222 Against Omicron BA.4/BA.5 Compared with Young Adults (Study P301)

End point title	Part 3 SRR of Serum Pseudovirus nAb Post Dose 1 of mRNA-1273.222 Against Omicron BA.4/BA.5 Compared with Young Adults (Study P301)[26]

End point description:

Seroresponse from pre Dose 1 Baseline at a participant level was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold rise if Baseline was equal to or above the LLOQ. P301 mRNA-1273 group included young adults (≥18 and ≤25 years) who received 2 doses of mRNA-1273 in P301 Part A and who were baseline SARS-CoV-2 negative in P301 Part A. PPIS-POS: all participants who received Dose 1 of mRNA-1273.222, had both Baseline (pre Dose 1) and Day 29 antibody assessment, had no major protocol deviations that impacted key or critical data, had not received off-study COVID-19 vaccination prior to Day 29 Visit, and who were SARS-CoV-2 positive (serologic and/or virologic evidence of prior SARS-CoV-2 infection) at baseline. 'Overall number of participants analyzed = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 29 Study P203/Day 57 Study P301

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 3: mRNA-1273.222 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	372	294		
Units: percentage of participants				
number (confidence interval 95%)	95.4 (92.8 to 97.3)	0.0 (0.0 to 1.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3 GM Value of Post Dose 1 (Day 29) of mRNA-1273.222 bAb Against Other Variants of Interest

End point title	Part 3 GM Value of Post Dose 1 (Day 29) of mRNA-1273.222 bAb Against Other Variants of Interest[27]

End point description:

mRNA-1273.222 bAb was measured using a S-binding IgG immunoassay. Antibody values reported as below the LLOQ were replaced by 0.5 * LLOQ. Values greater than the ULOQ are replaced by the ULOQ if actual values are not available (LLOQ: 397 AU/ml, ULOQ: 2200000 AU/mL). PPIS: all participants who received Dose 1 of mRNA-1273.222 and had both Baseline (pre Dose 1) and Day 29 antibody assessment, had no major protocol deviations that impacted key or critical data; and had not received off-study COVID-19 vaccination prior to Day 29 visit.

End point type	Secondary

End point timeframe:

Day 29

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 3: mRNA-1273.222 50 µg			
Subject group type	Reporting group			
Number of subjects analysed	372			
Units: AU/mL				
geometric mean (confidence interval 95%)				
BA.5 (n=372)	282734.2 (266581.0 to 299866.1)			
AY.4 (n=372)	557963.4 (529270.6 to 588211.6)			
B.1.1.7 (n=372)	434879.0 (412699.2 to 458250.8)			
B.1.351 (n=372)	431476.5 (409656.1 to 454459.1)			
B.1.1.529 (n=372)	189826.0 (178578.0 to 201782.5)			
P.1 (n=372)	471868.9 (446431.3 to 498756.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1C-2 GM Value of mRNA-1273 booster Against Variants of Interest at Day 29

End point title	Part 1C-2 GM Value of mRNA-1273 booster Against Variants of Interest at Day 29[28]

End point description:

End point type	Secondary

End point timeframe:

Day 29

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1C-2: mRNA-1273 50 µg BD			
Subject group type	Reporting group			
Number of subjects analysed	0[29]			
Units: AU/mL				
geometric mean (confidence interval 95%)	(to)			

Notes:

[29] - Data not collected due to discontinuation of enrollment.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 A GM Level of SARS-CoV-2 Spike Protein-specific bAb at Days 1, 57, 209, 394

End point title	Part 1 A GM Level of SARS-CoV-2 Spike Protein-specific bAb at Days 1, 57, 209, 394[30]

End point description:

SARS-CoV-2 Spike Protein-specific binding antibody (bAb) were measured using MesoScale Discovery (MSD) electrochemiluminescence multiplex assay. Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ are replaced by the ULOQ if actual values are not available (LLOQ: 69, ULOQ: 14400000). PPIS for long term analysis included all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Days 1, 57, 209, 394

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg			
Subject group type	Reporting group			
Number of subjects analysed	369			
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 1 (n=369)	65.848 (60.348 to 71.850)			
Day 57 (n=366)	346830.736 (330758.387 to 363684.079)			
Day 209 (n=366	79624.290 (73959.321 to 85723.172)			
Day 394 (n=356)	58647.246 (52309.921 to 65752.336)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1A GM Value of SARS-CoV-2-Specific nAb at Days 1, 57, 209, 394

End point title	Part 1A GM Value of SARS-CoV-2-Specific nAb at Days 1, 57, 209, 394[31]

End point description:

SARS-CoV-2-Specific nAb were measured using PsVNA assay. Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ are replaced by the ULOQ if actual values are not available (LLOQ: 10, ULOQ: 281600). PPIS for long term analysis included all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Days 1, 57, 209, 394

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As prespecified in the protocol, no statistical analysis was conducted for this endpoint.

End point values	Part 1A: mRNA-1273 100 µg			
Subject group type	Reporting group			
Number of subjects analysed	369			
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 1 (n=369)	11.249 (10.712 to 11.812)			
Day 57 (n=366)	1868.363 (1758.809 to 1984.742)			
Day 209 (n=366)	625.363 (583.319 to 670.437)			
Day 394 (n=363)	550.262 (489.875 to 618.093)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1C-1 GM Value of Post-booster Dose Serum bAb Against Variants of Interest (B.1.1.7, B.1.351, B.1.617.2, and P.1) as Measured by MSD

End point title	Part 1C-1 GM Value of Post-booster Dose Serum bAb Against Variants of Interest (B.1.1.7, B.1.351, B.1.617.2, and P.1) as Measured by MSD

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available. B.1.1.7 (LLOQ: 52, ULOQ: 8800000), B.1.351 (LLOQ: 111, ULOQ: 5000000), B.1.617.2 (LLOQ: 49, ULOQ: 7400000), P.1 (LLOQ: 143, ULOQ: 5800000). PPIS: all randomized participants who received planned doses of study drug per schedule, complied with immunogenicity testing schedule, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

BD Day 29

End point values	Part 1C-1: mRNA-1273 50 µg BD			
Subject group type	Reporting group			
Number of subjects analysed	324			
Units: AU/mL				
geometric mean (confidence interval 95%)				
B.1.1.7	581097.8 (543987.7 to 620739.5)			
B.1.351	431569.2 (404983.2 to 459900.6)			
B.1.617.2	456423.3 (429083.9 to 485504.8)			
P.1	417277.2 (391682.5 to 444544.5)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to EOS (Day 751)

Adverse event reporting additional description:

All-cause mortality: enrolled; AEs: participants received 1 dose of study drug.
Non-serious SARs persisting beyond 7 days, leading to discontinuation, or medically attended were defined as AEs in Part 1/2 but not in Part 3. COVID-19/SARS-CoV-2 infections were AEs in Part 1/2 but were considered clinical events for efficacy in Part 3 and not AEs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Part 1A: Placebo

Reporting group description:

Participants received 2 doses of placebo by IM injection (Day 1 and Day 29).

Reporting group title	Part 1A: mRNA-1273 100 µg

Reporting group description:

Participants received 2 doses of 100 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Reporting group title	Part 1 B: mRNA-1273 100 µg

Reporting group description:

Participants previously received 2 doses of placebo in the blinded phase and then received crossover vaccination with 100 µg of mRNA-1273.

Reporting group title	Part 2: mRNA-1273 50 ug BD

Reporting group description:

Participants received open-label mRNA-1273 50 µg in Part 2 and then a single BD of 50 µg mRNA-1273 IM injection on BD Day 1 in Part 2.

Reporting group title	Part 3: mRNA-1273.222 50 ug Second Dose

Reporting group description:

Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1). and a second dose approximately 6 months after the first dose (Day 181).

Reporting group title	Part 2: mRNA-1273 50 µg

Reporting group description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection (Day 1 and Day 29).

Reporting group title	Part 1C-2: mRNA-1273 50 µg BD

Reporting group description:

Participants who completed primary COVID-19 vaccination series with a non-Moderna vaccine under EUA, received a single booster of 50 µg mRNA-1273 IM injection on BD Day 1.

Reporting group title	Part 1C-1: mRNA-1273 50 µg BD

Reporting group description:

Participants received mRNA-1273 100 µg in blinded or cross-over phase and then a single booster of 50 µg mRNA-1273 IM injection on Booster Dose Day 1.

Reporting group title	Part 3: mRNA1273.222 50 µg 1 Dose

Reporting group description:

Participants received 1 dose of mRNA-1273.222 50 µg by IM injection (Day 1).

Serious adverse events	Part 1A: Placebo	Part 1A: mRNA-1273 100 µg	Part 1 B: mRNA-1273 100 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 1240 (0.32%)	21 / 2486 (0.84%)	2 / 96 (2.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haematoma			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			

subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emotional distress			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 1240 (0.00%)	2 / 2486 (0.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1240 (0.00%)	5 / 2486 (0.20%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 1240 (0.08%)	3 / 2486 (0.12%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical vertebral fracture			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sunburn			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic injury			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			

subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syringomyelia			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arnold-Chiari malformation			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiogenic shock	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Status migrainosus			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			

subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 1240 (0.08%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			

subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	1 / 1240 (0.08%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amoebic dysentery			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Murine typhus			
subjects affected / exposed	0 / 1240 (0.00%)	1 / 2486 (0.04%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 1240 (0.08%)	2 / 2486 (0.08%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: mRNA-1273 50 ug BD	Part 3: mRNA-1273.222 50 ug Second Dose	Part 2: mRNA-1273 50 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (0.00%)	4 / 335 (1.19%)	0 / 52 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 19 (0.00%)	2 / 335 (0.60%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haematoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emotional distress			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Concussion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sunburn			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic injury			

subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syringomyelia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arnold-Chiari malformation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiogenic shock	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Status migrainosus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			

subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amoebic dysentery			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Murine typhus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			

subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1C-2: mRNA-1273 50 µg BD	Part 1C-1: mRNA-1273 50 µg BD	Part 3: mRNA1273.222 50
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 155 (1.94%)	9 / 1408 (0.64%)	12 / 388 (3.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 155 (0.65%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haematoma			

subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emotional distress			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 155 (0.00%)	2 / 1408 (0.14%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Clavicle fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sunburn			

subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic injury			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syringomyelia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arnold-Chiari malformation			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiogenic shock	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Status migrainosus			

subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 155 (0.65%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation	Additional description: Sponsor assessment was Not related based on medical history, results of the heart biopsy, including findings of long-standing pre-existing heart failure and long time to onset (256 days).		
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 155 (0.65%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Amoebic dysentery			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Murine typhus			

subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	5 / 388 (1.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	1 / 388 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			

subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part 1A: Placebo	Part 1A: mRNA-1273 100 µg	Part 1 B: mRNA-1273 100 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	155 / 1240 (12.50%)	943 / 2486 (37.93%)	22 / 96 (22.92%)
Nervous system disorders			
Headache			
subjects affected / exposed	51 / 1240 (4.11%)	117 / 2486 (4.71%)	1 / 96 (1.04%)
occurrences (all)	57	129	1
General disorders and administration site conditions			
Injection site lymphadenopathy			
subjects affected / exposed	6 / 1240 (0.48%)	137 / 2486 (5.51%)	0 / 96 (0.00%)
occurrences (all)	6	146	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 1240 (0.24%)	8 / 2486 (0.32%)	0 / 96 (0.00%)
occurrences (all)	3	9	0
Skin and subcutaneous tissue disorders			
Mechanical urticaria			
subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			

subjects affected / exposed	0 / 1240 (0.00%)	0 / 2486 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 1240 (0.24%)	58 / 2486 (2.33%)	1 / 96 (1.04%)
occurrences (all)	3	60	1
Attention deficit hyperactivity disorder			
subjects affected / exposed	6 / 1240 (0.48%)	41 / 2486 (1.65%)	0 / 96 (0.00%)
occurrences (all)	6	41	0
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	4 / 1240 (0.32%)	11 / 2486 (0.44%)	0 / 96 (0.00%)
occurrences (all)	4	12	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1240 (0.00%)	3 / 2486 (0.12%)	1 / 96 (1.04%)
occurrences (all)	0	3	1
COVID-19			
subjects affected / exposed	34 / 1240 (2.74%)	382 / 2486 (15.37%)	11 / 96 (11.46%)
occurrences (all)	35	383	11
Influenza			
subjects affected / exposed	0 / 1240 (0.00%)	19 / 2486 (0.76%)	1 / 96 (1.04%)
occurrences (all)	0	20	1
Nasopharyngitis			
subjects affected / exposed	6 / 1240 (0.48%)	60 / 2486 (2.41%)	4 / 96 (4.17%)
occurrences (all)	6	64	4
Asymptomatic COVID-19			
subjects affected / exposed	25 / 1240 (2.02%)	81 / 2486 (3.26%)	6 / 96 (6.25%)
occurrences (all)	25	82	6
Tooth abscess			
subjects affected / exposed	0 / 1240 (0.00%)	2 / 2486 (0.08%)	0 / 96 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	28 / 1240 (2.26%)	257 / 2486 (10.34%)	3 / 96 (3.13%)
occurrences (all)	32	293	3

Non-serious adverse events	Part 2: mRNA-1273 50 ug BD	Part 3: mRNA-1273.222 50 ug Second Dose	Part 2: mRNA-1273 50 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 19 (36.84%)	51 / 335 (15.22%)	12 / 52 (23.08%)
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 19 (0.00%)	5 / 335 (1.49%)	1 / 52 (1.92%)
occurrences (all)	0	5	1
General disorders and administration site conditions			
Injection site lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Mechanical urticaria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Parapsoriasis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 19 (5.26%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	3 / 52 (5.77%)
occurrences (all)	0	0	3
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	22 / 335 (6.57%)	0 / 52 (0.00%)
occurrences (all)	0	30	0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 335 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0

COVID-19			
subjects affected / exposed	3 / 19 (15.79%)	0 / 335 (0.00%)	3 / 52 (5.77%)
occurrences (all)	3	0	3
Influenza			
subjects affected / exposed	2 / 19 (10.53%)	0 / 335 (0.00%)	1 / 52 (1.92%)
occurrences (all)	2	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	23 / 335 (6.87%)	0 / 52 (0.00%)
occurrences (all)	0	26	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 19 (0.00%)	0 / 335 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Tooth abscess			
subjects affected / exposed	1 / 19 (5.26%)	1 / 335 (0.30%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 335 (0.00%)	2 / 52 (3.85%)
occurrences (all)	1	0	2

Non-serious adverse events	Part 1C-2: mRNA-1273 50 µg BD	Part 1C-1: mRNA-1273 50 µg BD	Part 3: mRNA1273.222 50
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 155 (18.06%)	429 / 1408 (30.47%)	77 / 388 (19.85%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 155 (0.65%)	28 / 1408 (1.99%)	20 / 388 (5.15%)
occurrences (all)	1	29	27
General disorders and administration site conditions			
Injection site lymphadenopathy			
subjects affected / exposed	0 / 155 (0.00%)	5 / 1408 (0.36%)	0 / 388 (0.00%)
occurrences (all)	0	5	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 155 (0.00%)	6 / 1408 (0.43%)	1 / 388 (0.26%)
occurrences (all)	0	6	1
Skin and subcutaneous tissue disorders			

Mechanical urticaria			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 1408 (0.00%)	0 / 388 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 155 (0.65%)	26 / 1408 (1.85%)	0 / 388 (0.00%)
occurrences (all)	1	27	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	2 / 155 (1.29%)	14 / 1408 (0.99%)	0 / 388 (0.00%)
occurrences (all)	2	14	0
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	1 / 155 (0.65%)	2 / 1408 (0.14%)	26 / 388 (6.70%)
occurrences (all)	1	2	34
Parainfluenzae virus infection			
subjects affected / exposed	1 / 155 (0.65%)	2 / 1408 (0.14%)	1 / 388 (0.26%)
occurrences (all)	1	2	1
COVID-19			
subjects affected / exposed	10 / 155 (6.45%)	257 / 1408 (18.25%)	0 / 388 (0.00%)
occurrences (all)	10	267	0
Influenza			
subjects affected / exposed	7 / 155 (4.52%)	30 / 1408 (2.13%)	5 / 388 (1.29%)
occurrences (all)	8	30	6
Nasopharyngitis			
subjects affected / exposed	0 / 155 (0.00%)	16 / 1408 (1.14%)	30 / 388 (7.73%)
occurrences (all)	0	17	34
Asymptomatic COVID-19			
subjects affected / exposed	2 / 155 (1.29%)	39 / 1408 (2.77%)	0 / 388 (0.00%)
occurrences (all)	2	39	0
Tooth abscess			
subjects affected / exposed	0 / 155 (0.00%)	1 / 1408 (0.07%)	0 / 388 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			

subjects affected / exposed occurrences (all)	6 / 155 (3.87%) 8	81 / 1408 (5.75%) 101	4 / 388 (1.03%) 4

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 March 2021	- Addition of the crossover design - Study design was updated to describe the updated crossover design of the study, including Part A (the Blinded Phase) and Part B (the Open-label Observational Phase).
27 July 2021	- Added CDC case definitions for myocarditis and pericarditis. - Added assessment of risk of myocarditis and pericarditis.
04 November 2021	- Added Part C to the study. - Updated long-term analysis and Booster Phase analysis. - Addition of booster interim analyses. - Added nasal swab for samples for SARS-CoV-2. - Clarified that only Part A and Part C will have primary immunogenicity analyses.
25 January 2022	- Added Part 1C-2 and Part 2.
11 October 2022	- Modifications to primary objectives and endpoints, secondary endpoints, statistical hypothesis, power and sample size, analysis, and procedures in Part 2 of the study. - Clarified that immunogenicity hypothesis testing will not be performed for Part 2. - Discontinuation of enrollment in Part 1C-2 and Part 2 of the study. - Clarified that Convalescent Visits are applicable to Part 1A and 1B only. - Removed BD from Part 2 and convalescent visits from Part 1C-1, Part 1C-2, and Part 2 of the study. - Added an open-label Part 3 of the study. - Updated exclusion criteria. - Updated study assessments and procedures.
22 June 2023	-Modifications to primary and (key) secondary immunogenicity objectives and endpoints, statistical hypothesis, power and sample size, and analysis in Part 3 of the study. - Updated inclusion/exclusion criteria - Clarifying the definition of the SARS-CoV-2 status at baseline.
19 October 2023	- Updated Part 3 study design and objective to single dosing. - Updated to single dosing in Part 3. - Reduced safety follow-up duration for Part 3 participants who receive Dose 2. - Updated timepoints for collection of blood samples and nasopharyngeal or nasal swab samples. -Clarification of the end-of-study definition. - Clarification added on the time period for recording all concomitant medications and nonstudy vaccinations in the electronic case report form. - Updated safety assessments related to single dosing in Part 3. -Updated PP Immunogenicity Subset for Part 3. - Addition of schedule of assessments for Part 3 participants who receive only 1 dose. - Addition of schedule of assessments for Part 2 participants who receive the booster dose.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Part 1C-2 enrollment discontinued before planned number of participants. Part 2 discontinued early due to availability of updated variant vaccine (mRNA-1273.222); no hypothesis testing done for primary endpoint/other endpoints not assessed.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34379915

http://www.ncbi.nlm.nih.gov/pubmed/39091673

http://www.ncbi.nlm.nih.gov/pubmed/39332418