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Respiratory vaccines

Program Pack

COVID-19 (mRNA-1273/83)

Spikevax® & mNEXSPIKE® (mRNA-1273/1283): Moderna now has two approved products to protect against COVID-19

spikevax™ COVID-19 Vaccine, mRNA

- mRNA-1273: Our first approved vaccine

mNEXSPIKE® COVID-19 Vaccine, mRNA

- mRNA-1283: Our next-gen covid vaccine

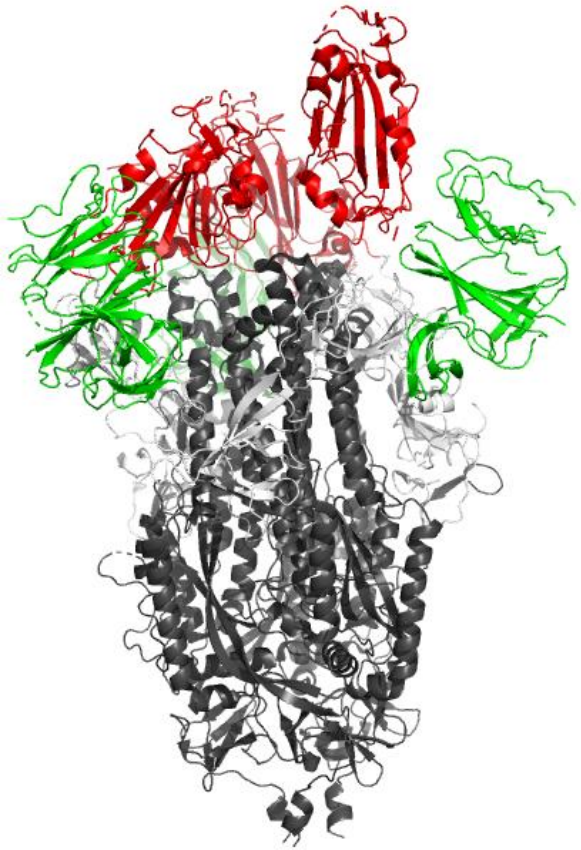
Our next generation COVID-19 vaccine mRNA-1283 is a significant leap forward in our respiratory vaccine strategy

mRNA-1283 encodes specifically for the Receptor Binding Doman (RBD) and N-Terminal Domain (NTD) of the spike protein

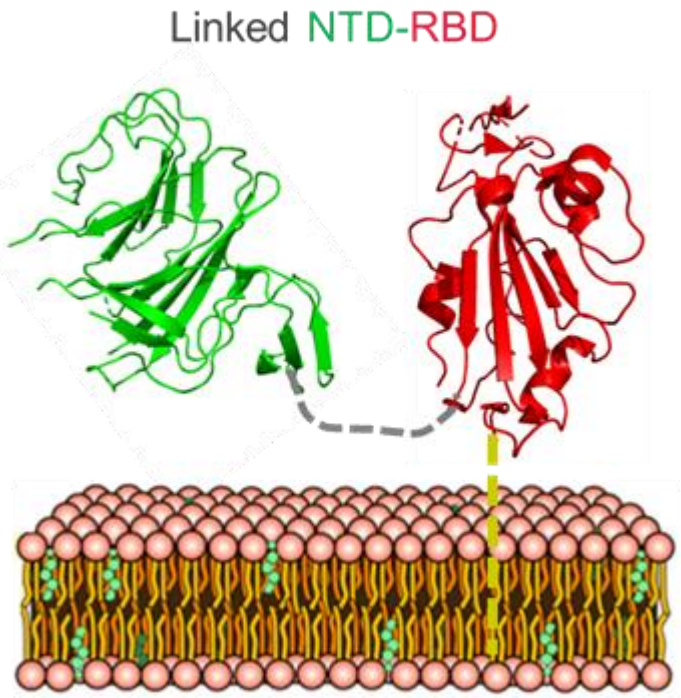
Enables combination vaccines and enhance overall respiratory portfolio

Offers a more competitive standalone COVID-19 vaccine, driven by refrigerator-stable pre-filled syringes (PFS)

mRNA-1273



mRNA-1283



mRNA-1283 pivotal Phase 3 trial design

The Phase 3 was designed to test the immunogenicity, safety and relative vaccine efficacy of mRNA-1283.222 against mRNA-1273.222 in participants 12+ years of age

Design
Randomized 1:1, observer-blind, active-controlled study

Number of participants dosed
11,417 medically stable adults ≥ 12 years old

Vaccination schedule
Single dose of mRNA-1283.222 or mRNA-1273.222

Bivalent vaccine encoding the ancestral and BA.4/5

Duration:
Study participants will be followed up for 12 months after study injection

Site location
US, UK and Canada

Total N= 11,417
Randomization Ratio = 1:1

mRNA-1283.222
n = 5,706

mRNA-1273.222
n = 5,711

Relative vaccine efficacy (rVE) of mRNA-1283 vs mRNA-1273: success criterion met

Per-Protocol Set for Efficacy

	mRNA-1283 (10 µg) N = 5679	**mRNA-1273 (50 µg)** N = 5687
Number of participants with COVID-19, n (%)	**9.9%** (560)	**10.8%** (617)
Person-months	**40,778**	**40,782**
Incidence rate per 100 person-months (95% CI)	**1.4** (1.3, 1.5)	**1.5** (1.4, 1.6)
Relative Vaccine Efficacy Based on Hazard Ratio (99.4% CI)[1,2]	**9.3% (-6.6, 22.8)**	
p-value[3]	**0.0005**	

Based on CDC COVID-19 definition
1 rVE =1-hazard ratio, hazard ratio estimated using a stratified Cox proportional hazard model (stratified by age group at randomization) and with treatment group as a fixed effect.
2 Alpha-adjusted 2-sided (99.4%) CI was calculated using the Lan-DeMets O'Brien-Fleming Spending function (nominal one-sided alpha of 0.0028)
3 P-value based on the stratified Cox proportional hazard model to test the null hypothesis log (hazard ratio)>=log(1.1)

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Relative vaccine efficacy of mRNA-1283 vs mRNA-1273 by age group

COVID-19 Events through 31 Jan 2024 - Per-Protocol Set for Efficacy

	12-17 years		18-64 years		≥65 Years	
	mRNA-1283 10 µg N = 491	**mRNA-1273 50 µg** N = 490	**mRNA-1283 10 µg** N = 3558	**mRNA-1273 50 µg** N = 3562	**mRNA-1283 10 µg** N = 1630	**mRNA-1273 50 µg** N = 1635
Number of Participants with COVID-19	**5.9%** (29)	**4.7%** (23)	**10.7%** (382)	**11.8%** (422)	**9.1%** (149)	**10.5%** (172)
Incidence rate per 100 person-months (95% CI)	**1.0** (0.7, 1.5)	**0.8** (0.5, 1.2)	**1.4** (1.3, 1.6)	**1.6** (1.5, 1.8)	**1.3** (1.1, 1.5)	**1.5** (1.3, 1.7)
Relative Vaccine Efficacy (95% CI)	**-29.2%** (-123.3, 25.3)		**9.7%** (-3.8, 21.3)		**13.5%** (-7.7, 30.6)	

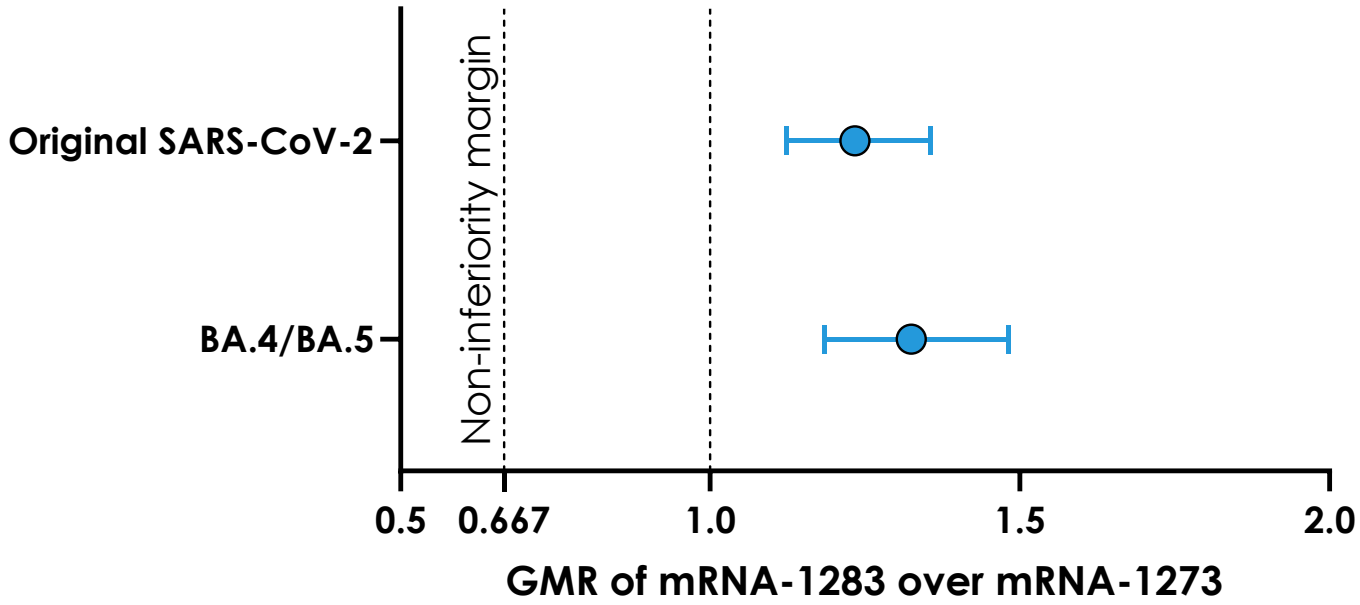
Based on CDC COVID-19 definition

1 rVE =1-hazard ratio, hazard ratio estimated using a stratified Cox proportional hazard model (stratified by age group at randomization) and with treatment group as a fixed effect.
2 Alpha-adjusted 2-sided (99.4%) CI was calculated using the Lan-DeMets O'Brien-Fleming Spending function (nominal one-sided alpha of 0.0028)
3 P-value based on the stratified Cox proportional hazard model to test the null hypothesis log (hazard ratio)>=log(1.1)

mRNA-1283.222 elicited higher antibody response against both BA.4/5 and original SARS-CoV-2 compared to mRNA-1273.222

Geometric mean ratio (GMR) of mRNA-1283.222 vs mRNA-1273.222 against BA.4/BA.5 and original SARS-CoV-2 based on a randomly selected immunogenicity subset*

- mRNA-1283 arm (N=621), mRNA-1273 arm (n=568)



Success Criteria Met

- GMR[1] non inferiority:
  Lower 95% CI of GMR >0.667
- Seroresponse rate[2] difference non-inferiority:
  Lower 95% CI of difference > -10%

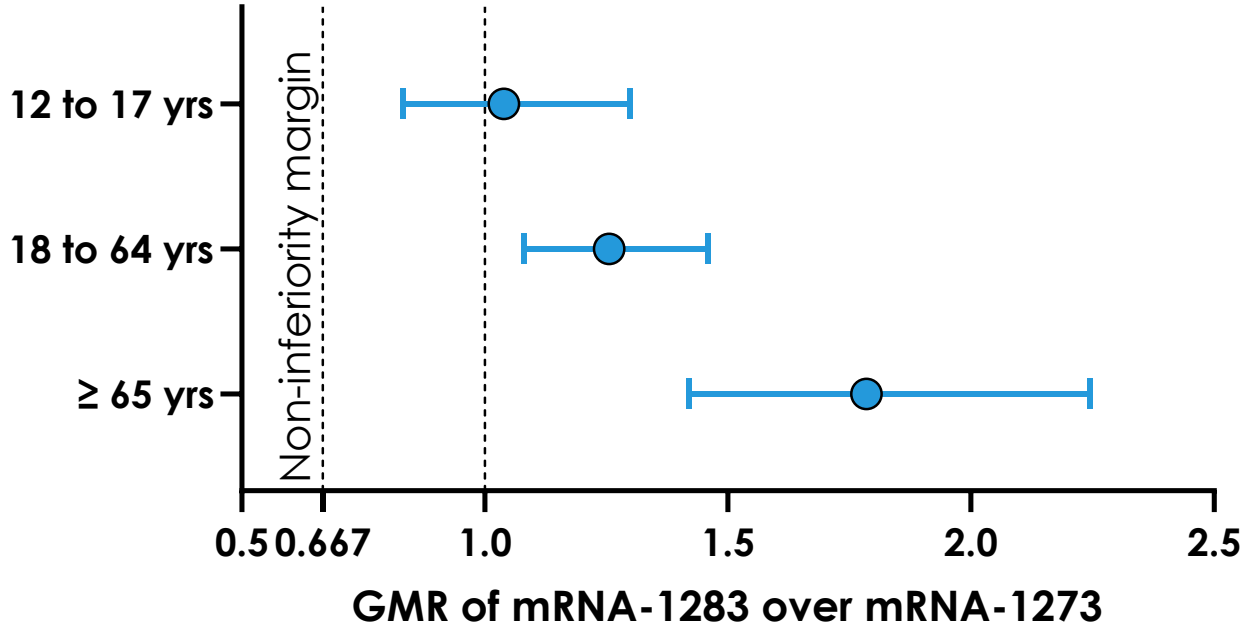
* Per protocol immunogenicity subset was used to assess immunogenicity objectives. The PPIS consisted participants from immunogenicity subset) who received the planned dose of study vaccination, have pre-booster and Day 29 neutralizing antibody data, and had no major protocol deviations that impact immunogenicity data.

1 ANCOVA model adjusting for SARS-CoV-2 infection status pre-vaccination, randomization age group, number of prior doses and type of last COVID-19 vaccine (mRNA Omicron bivalent, mRNA original monovalent, non-mRNA vaccine). Coefficients for Least Square Means use margins.

2 Seroresponse primary definition = an antibody value change from baseline below the LLOQ to >=4 × LLOQ, or at least a 4-fold rise if baseline is >= LLOQ and <4 × LLOQ, or at least a 2-fold rise if baseline is >=4 × LLOQ; 3 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits

mRNA-1283.222 antibody response against BA.4/5 compared to mRNA-1273.222 by age group

Geometric mean ratio (GMR) of mRNA-1283.222 vs mRNA-1273.222 against BA.4/BA.5 based on a randomly selected immunogenicity subset*



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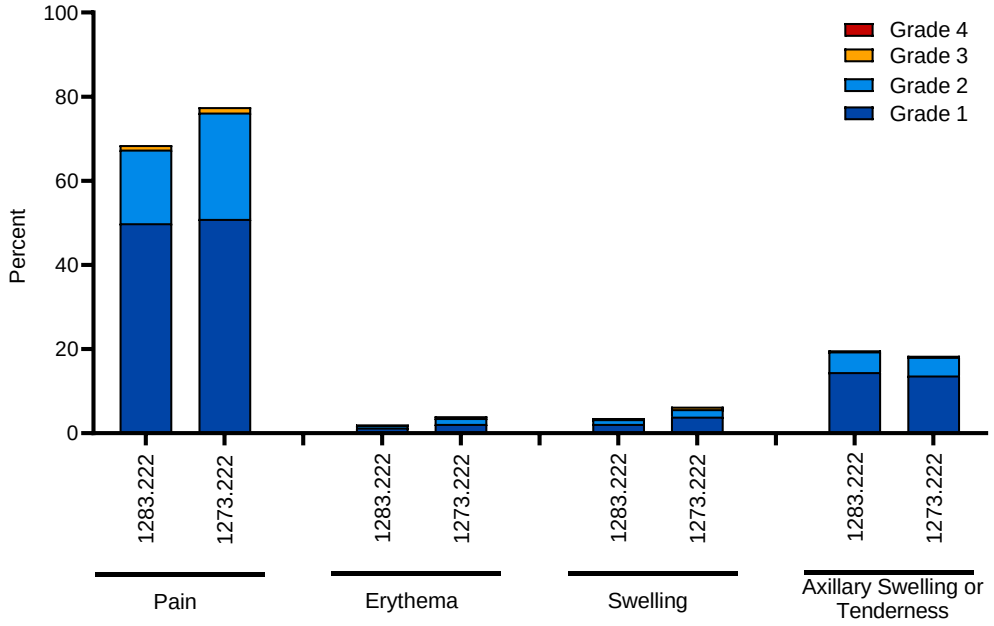
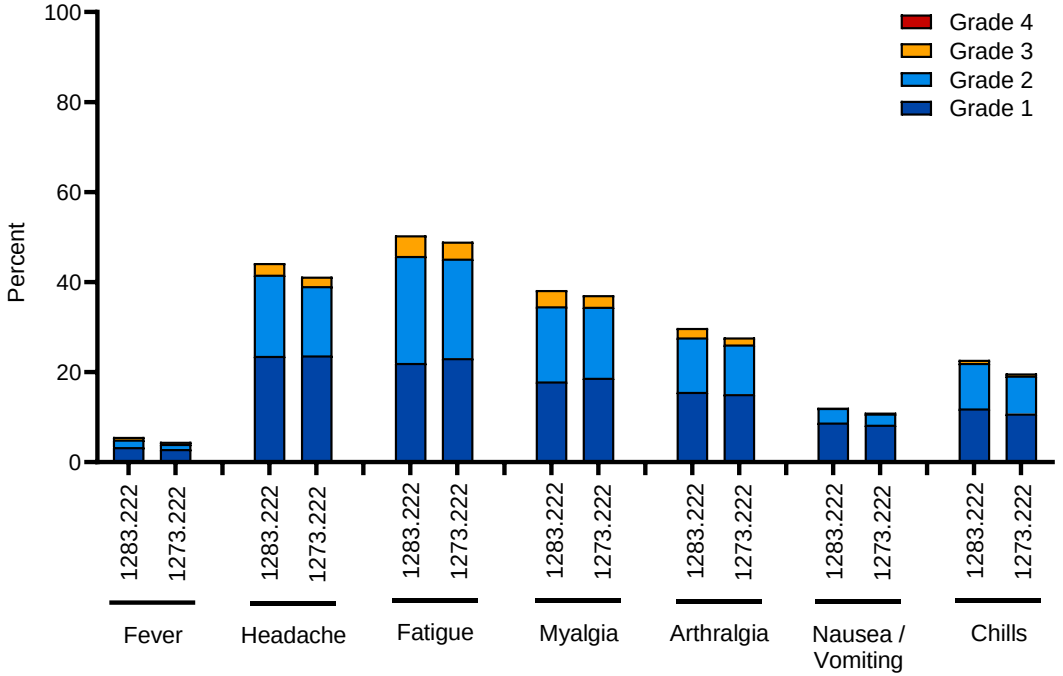
Reactogenicity profile of mRNA-1283 similar to mRNA-1273

Overall Local Reactogenicity: 70.3% mRNA-1283.222 vs. 78.4% mRNA-1273.222



Solicited Safety Set: 1283.222 N=5707, 1273.222 N=5711

Overall Systemic Reactogenicity: 64.4% mRNA-1283.222 vs. 64.2% mRNA-1273.222



Solicited Safety Set: 1283.222 N=5707, 1273.222 N=5711

mRNA-1283 pivotal Phase 3 safety

mRNA-1283 was well-tolerated and its safety and reactogenicity profile was consistent with the known safety profile of mRNA-1273

No deaths or discontinuations of vaccination were reported as related to mRNA-1283

Myocarditis and pericarditis have rarely been reported with mRNA-1273 and are important identified risks for mRNA-1273. No events of myocarditis or pericarditis were reported for mRNA-1283 in clinical studies

Next-gen COVID-19 vaccine mRNA-1283 summary and next steps

Vaccine efficacy	• Pre-specified relative vaccine efficacy (rVE) objective met • rVE of mRNA-1283 non-inferior compared to mRNA-1273 • rVE point estimate highest in participants ≥ 65 years old
Immunogenicity	• Pre-specified immunogenicity objectives met • mRNA-1283.222 elicited higher titers against both BA.4/5 and original SARS-CoV-2 at a lower dose compared to mRNA-1273.222
Reactogenicity / Safety	• Local reactions trend lower with mRNA-1283 than mRNA-1273 • Systemic reactions following mRNA-1283 similar to mRNA-1273 • No safety concerns identified for mRNA-1283
Next steps	• Launch in the U.S., and obtain approvals ex-US

Medical and scientific presentations

ECSMID 2025 (mRNA-1283 vs. mRNA-1273)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/Covid-Poster-P301-Primary-Analysis-74.pdf

ECSMID 2025 (rVE of mRNA-1283 vs. mRNA-1273)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/Covid-Oal-mRNA-1283-P301-Subgroup-Analysis-45-Read-Only.pdf

ECSMID 2025 (immunogenicity of JN.1 and KP.2)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/COVID-1273-Oral-presentation-88-Read-Only.pdf

ECSMID 2025 (safety & immunogenicity in JP)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/COVID-Poster-P301-Japan-Data-Poster-30.pdf

Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the ability of Moderna's COVID-19 vaccines to provide protection against COVID-19 and variants of concern; Moderna's ability to produce new candidate vaccines for protection against emerging COVID variants; Moderna's launch of mNEXSPIKE in the US and potential ex-US approvals; and the potential of mRNA-1283 to make a significant leap forward in Moderna's respiratory vaccine strategy. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others, those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.