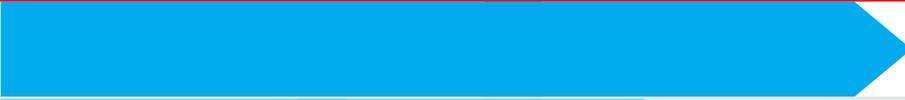


# COVID-19 vaccine (mRNA-1273)

Last program update: November 16, 2020

Modality	ID #	Program		Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
 <b>Prophylactic vaccines</b>	mRNA-1273	COVID-19 vaccine							Worldwide BARDA funded
	mRNA-1647	Cytomegalovirus (CMV) vaccine							Worldwide
	mRNA-1653	hMPV/PIV3 vaccine		Phase 1 (healthy volunteers)	Phase 1b (Age de-escalation) Seropositives				Worldwide
	mRNA-1893	Zika vaccine							Worldwide BARDA funded
	mRNA-1345	Pediatric respiratory syncytial virus (RSV) vaccine <i>Future respiratory combo</i>							Worldwide
	mRNA-1189	Epstein-Barr virus (EBV) vaccine							Worldwide
	mRNA-1851	Influenza H7N9 vaccine							Worldwide <i>Advancing subject to funding</i>

# Forward-looking Statements and Disclaimer

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This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the Company's development of a potential vaccine (mRNA-1273) against the novel coronavirus, mRNA-1273's efficacy and its ability to prevent infection or mitigate symptoms of COVID-19, the safety profile for mRNA-1273, the Company's plans to seek regulatory approval for the use of mRNA-1273 in the U.S. and other jurisdictions, the conditions under which mRNA-1273 can be shipped, stored and administered, the Company's sales of mRNA-1273 and the status of negotiations for such sales, and the Company's anticipated production of mRNA-1273. 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: the fact that there has never been a commercial product utilizing mRNA technology approved for use; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q 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](http://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.

# COVID-19 vaccine candidate (mRNA-1273) meets primary efficacy endpoint in the first interim analysis of the Phase 3 COVE Study

## Phase 3 study met statistical criteria with a vaccine efficacy of 94.5%

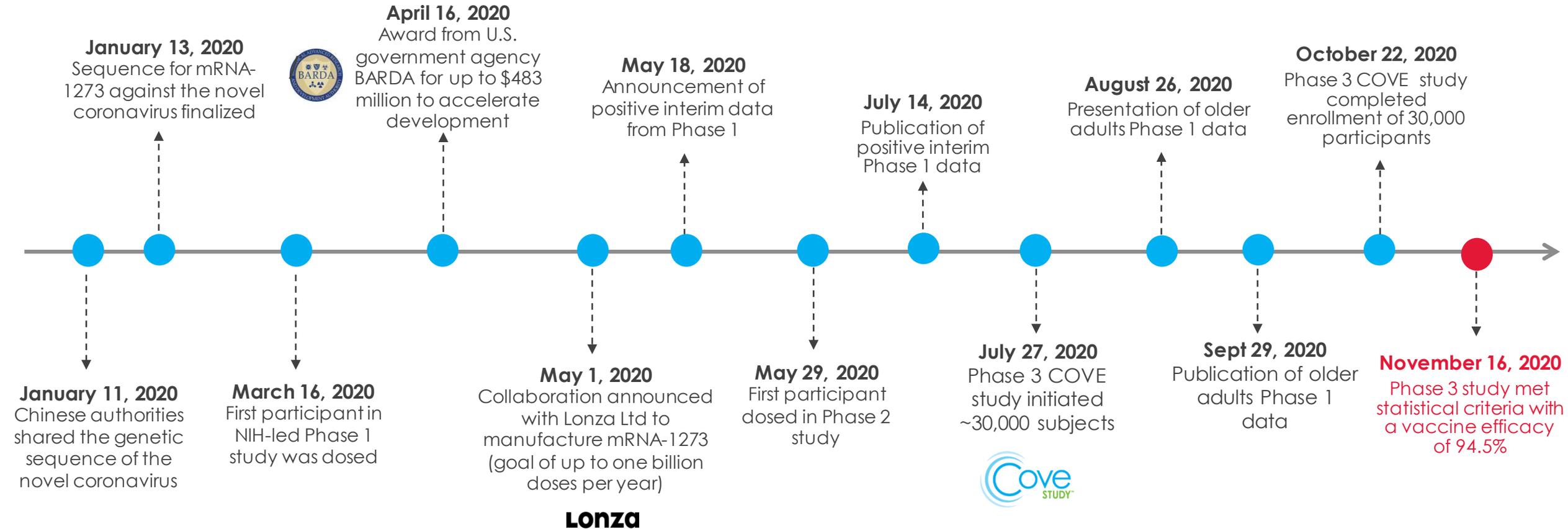
- Primary endpoint of the Phase 3 COVE study is based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine
  - Based on 95 cases, of which 90 cases of COVID-19 were observed in the placebo group versus 5 cases observed in the mRNA-1273 group, resulting in a point estimate of vaccine efficacy of 94.5% ( $p < 0.0001$ )
- Secondary endpoint analyzed severe cases of COVID-19 and included 11 severe cases (as defined in the study protocol)
  - All 11 cases occurred in the placebo group and none in the mRNA-1273 vaccinated group
- The 95 COVID-19 cases included 15 older adults (ages 65+) and 20 participants identifying as being from diverse communities (including 12 Hispanic or LatinX, 4 Black or African Americans, 3 Asian Americans and 1 multiracial)

## The DSMB did not report significant safety concerns during a concurrent review of the available safety data

- A review of solicited adverse events demonstrated that vaccine was generally well tolerated; majority of adverse events were mild or moderate in severity and the solicited adverse events were generally short lived<sup>1</sup>
  - Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%)

## Intend to submit for an Emergency Use Authorization (EUA) with the U.S. FDA in the coming weeks and anticipate having the EUA informed by the final safety and efficacy data (with a median duration of at least 2 months)

# COVID-19 vaccine (mRNA-1273) timeline through November 16, 2020



# Phase 1 trial overview

## Led by the National Institutes of Health (NIH)

### Key objective:

- To assess the safety, reactogenicity and immunogenicity of mRNA-1273

### Study design:

- Phase 1, open-label dose ranging clinical trial in healthy adults
- Subjects received an intramuscular (IM) injection (0.5 milliliter [mL]) of mRNA-1273 on Days 1 and 29 in the deltoid muscle and will be followed through 12 months post second vaccination (Day 394)

### Primary endpoint:

- Safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart

### Secondary endpoint:

- Evaluate the immunogenicity to the SARS-CoV-2 S protein following a 2-dose vaccination schedule of mRNA-1273 at Day 57

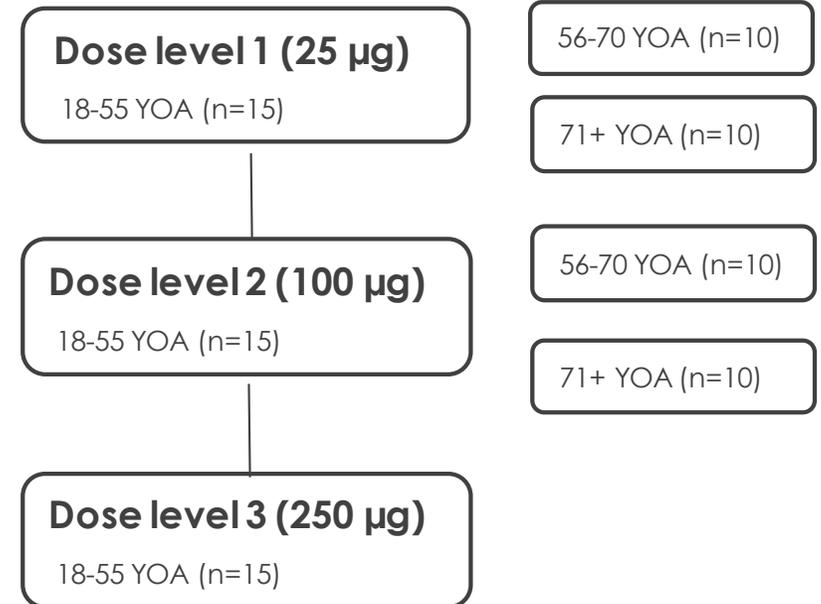
### Trial progress/details:

- Original 3 dose cohorts 25 µg, 100 µg and 250 µg (18-55 years old) Day 57 data published in *The New England Journal of Medicine*<sup>1</sup>
- Interim analysis of the 100 µg dose for the 56-70 and 71+ age cohorts presented at ACIP Meeting
- 50 µg dose across three age cohorts (18-55, 56-70 and 71+) are fully enrolled



### mRNA-1273-P101 Study Design

YOA = years of age



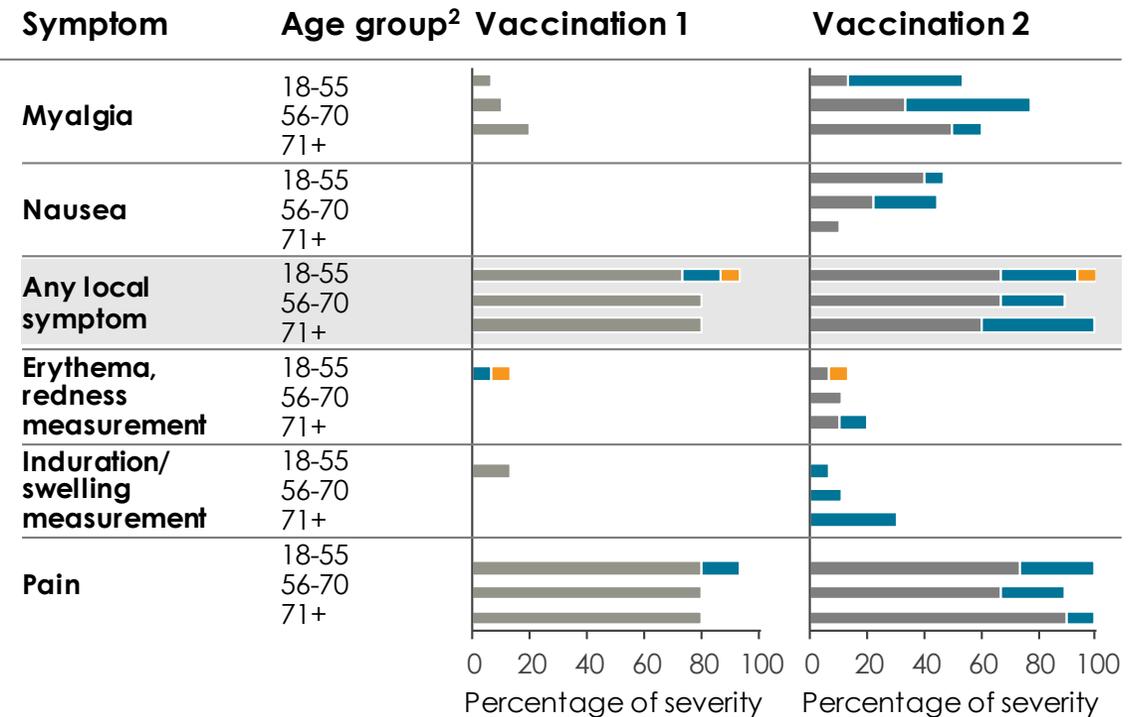
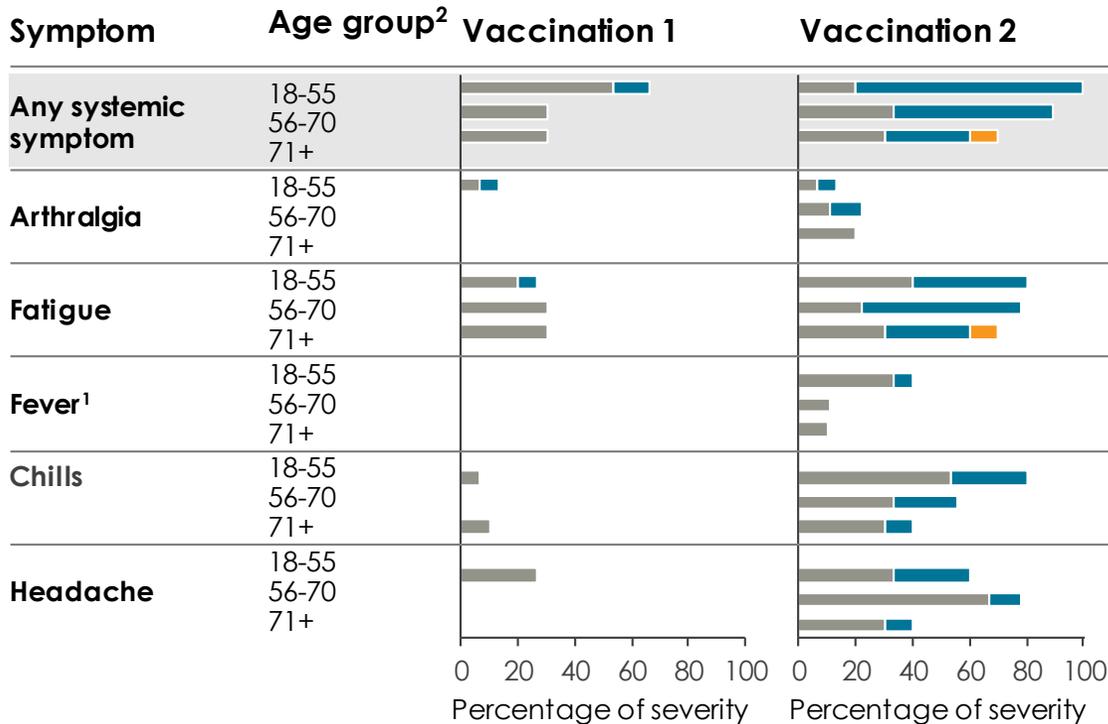
# Safety data from Phase 1 trial

■ Grade 1 (mild) ■ Grade 2 (moderate) ■ Grade 3 (severe)

## Phase 1: No Vaccine-Related SAEs Have Been Reported

Solicited Local and Systemic Symptoms Followed for 7 Days Post-vaccination

Majority of symptoms resolved within 2 days, some persisted as long as 5 days

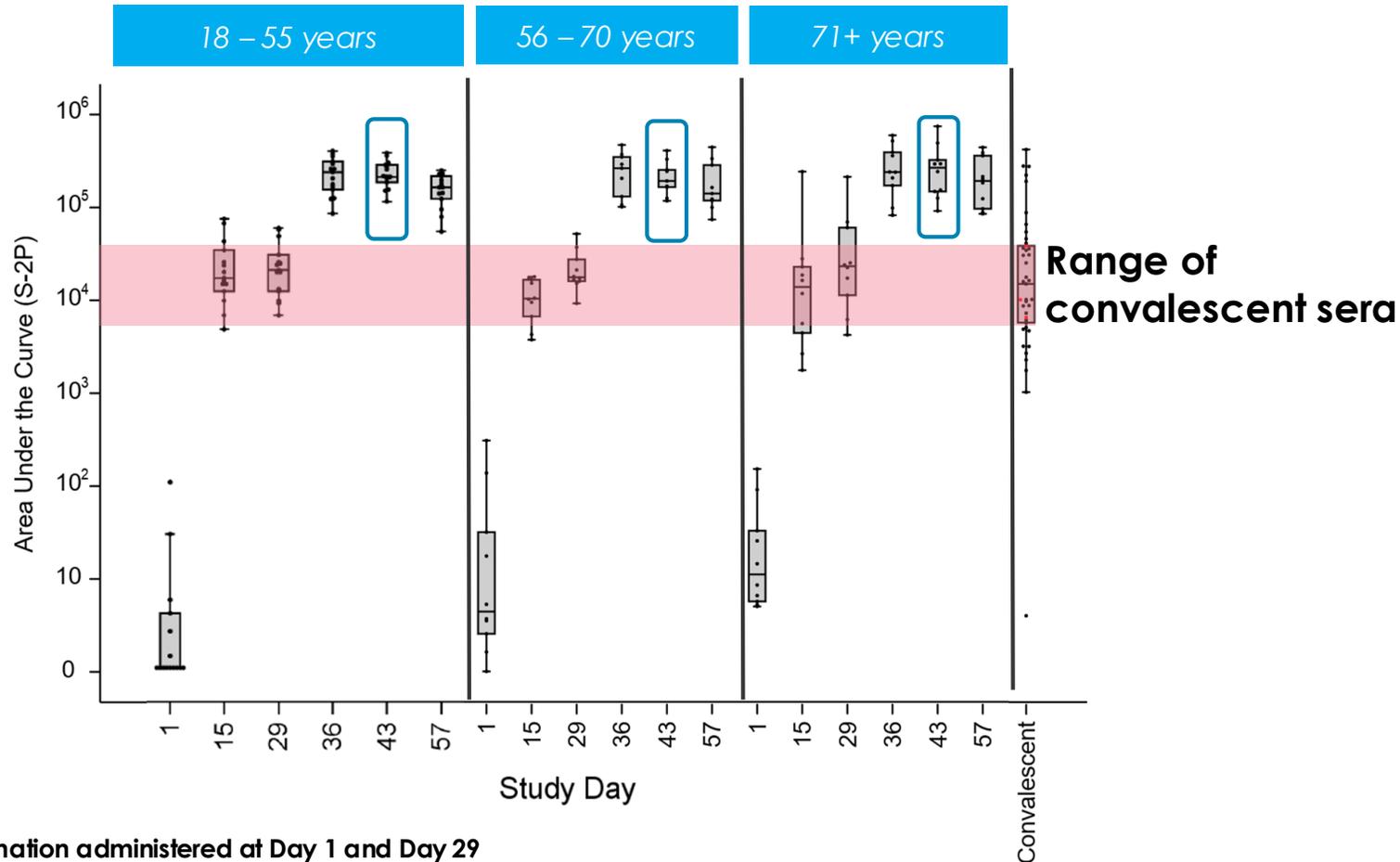


1. Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment

2. 18-55: N=15; 56-70: N=10; 71+: N=10; N = All subjects receiving Dose 1 with any solicited event data recorded in the database

# Binding antibodies comparable across age groups (Phase 1)

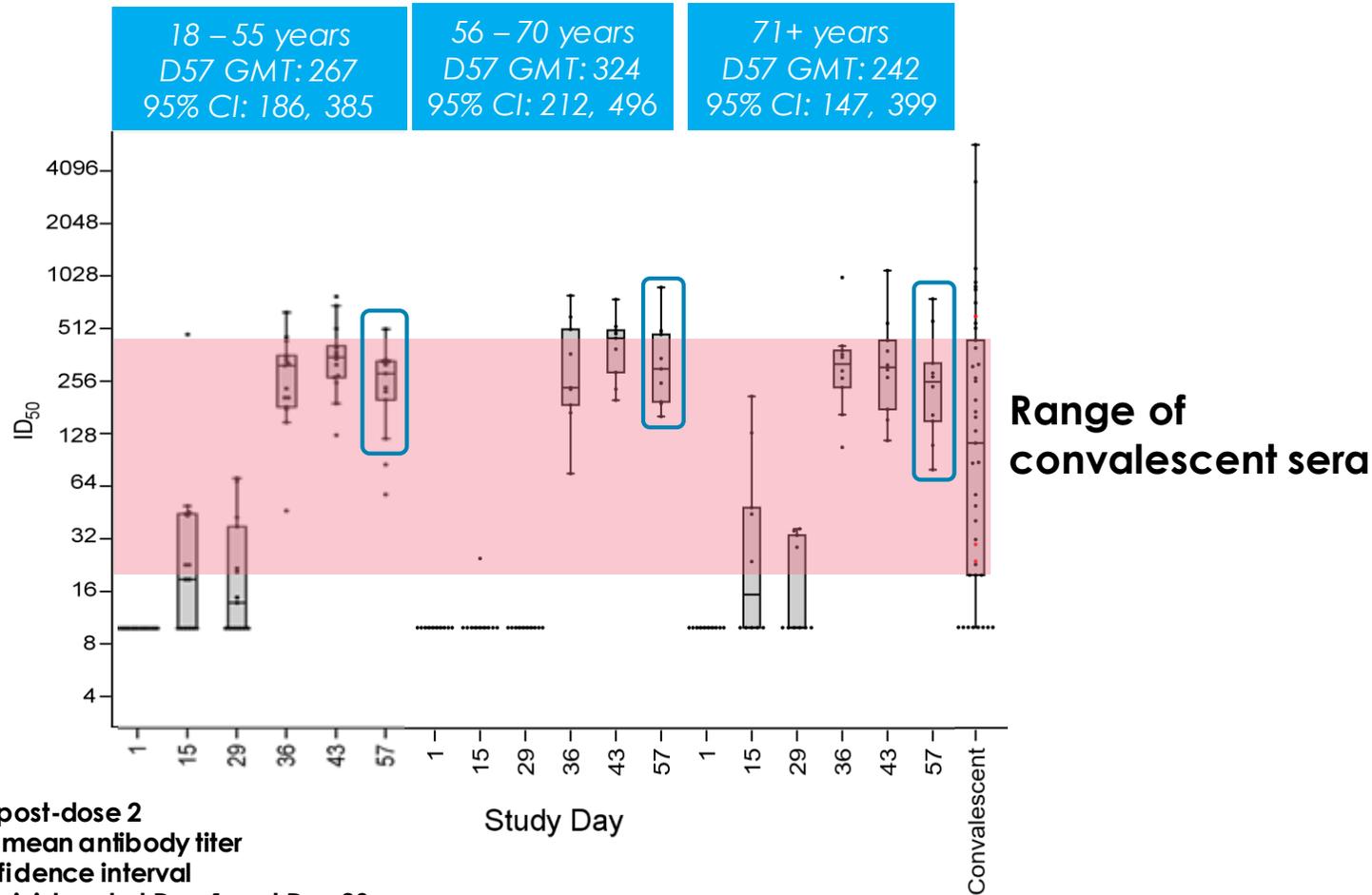
S-2P binding antibodies (ELISA)- 100 µg at Day 1 and Day 29



- 100 µg two-dose series seroconverted all participants after the first vaccination
- After the first vaccination, AUC for all age groups exceeded the median of convalescent sera
- After two vaccinations, all age groups are equivalent to high-titer convalescent sera (i.e., upper quartile)

# Distribution of antibody titers in pseudovirus neutralization assay comparable across age groups (Phase 1)

## Pseudovirus neutralization assay titers (ID<sub>50</sub>)- 100 µg at Day 1 and Day 29

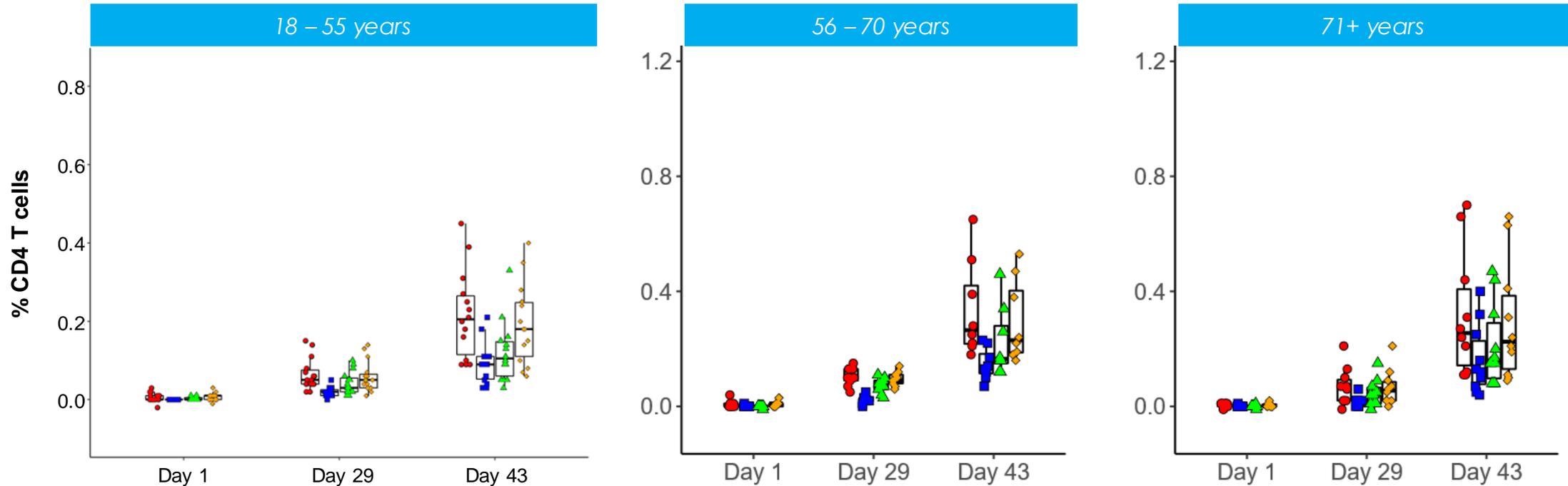
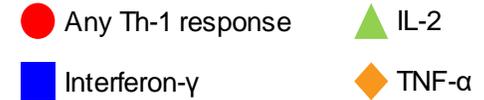


- After second vaccination, pseudovirus neutralization responses were detected in all participants
- Pseudovirus neutralization titers were comparable across age groups
- Pseudovirus neutralization titer for 56-70 and 71+ YOA above convalescent sera median titer at Day 57

**D57: one month post-dose 2**  
**GMT: geometric mean antibody titer**  
**95% CI: 95% confidence interval**  
**Vaccination administered at Day 1 and Day 29**

# mRNA-1273 elicited Th1-biased CD4 T cell responses in all participants (Phase 1)

## Th1 CD4+ T cell response, S1 peptide pool (100 µg at Day 1 and 29)



- Vaccination with 100 µg mRNA-1273 led a Th1-biased CD4+ T-cell response across all age groups
- Th2 phenotype was rare (data not shown)

# Pivotal Phase 3 efficacy, safety and immunogenicity study

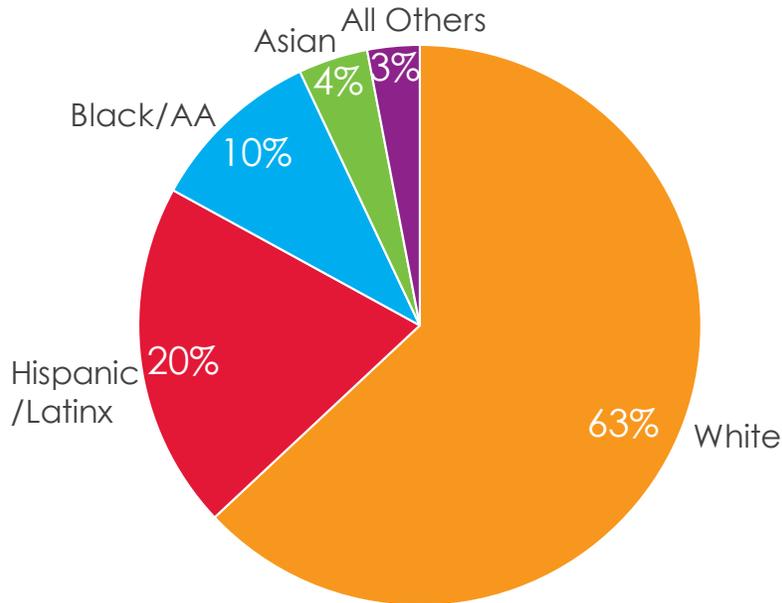
## Fully enrolled (N=30,000) on October 22<sup>nd</sup>

### Phase 3 trial overview (NCT04470427)

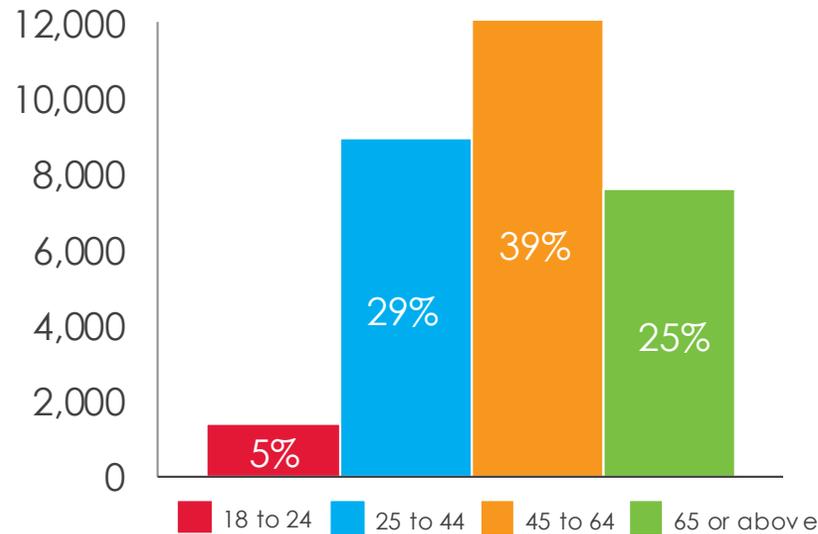
<b>Protocol Title</b>	A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older			
<b>Study Groups</b>	<b>Strata</b>	<b>Dosage IM (D1, D29) 1:1</b>	<b>Sample Size</b>	<b>Enrollment status</b>
	≥ 65 years	100 µg, placebo	42%	Enrollment completed October 22
	< 65 years at increased risk for complication of COVID-19 (“at risk”)	100 µg, placebo		
	< 65 years and not at risk	100 µg, placebo	58%	Enrollment completed October 22
<b>Participant Population</b>	Approximately 30,000 participants (case driven) whose locations or circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection “All-comers” with regard to SARS-CoV-2 serostatus (baseline serology will be collected)			
<b>Study Objectives</b>	To demonstrate the efficacy of mRNA-1273 to prevent COVID-19 To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart			
<b>Study Duration</b>	Approximately 25 months for each participant corresponding to a 24-month follow up after the last vaccine administration			

# COVE study successfully recruited diverse and representative participants

Race and ethnicity distribution

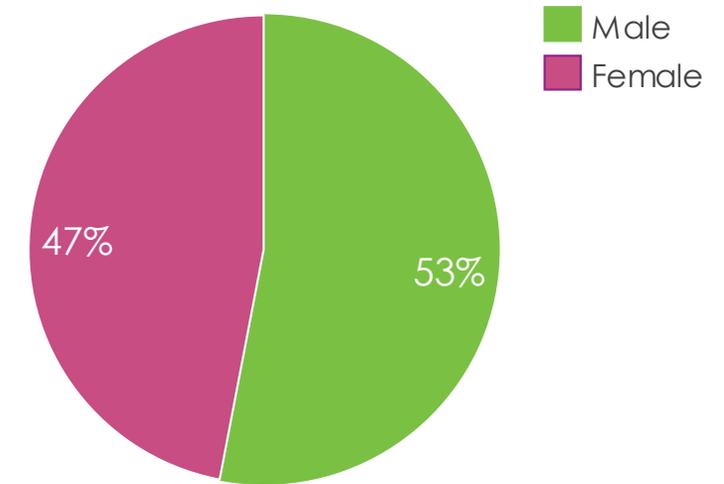


Age breakdown\*



\* Numbers may not add up to 100 due to rounding

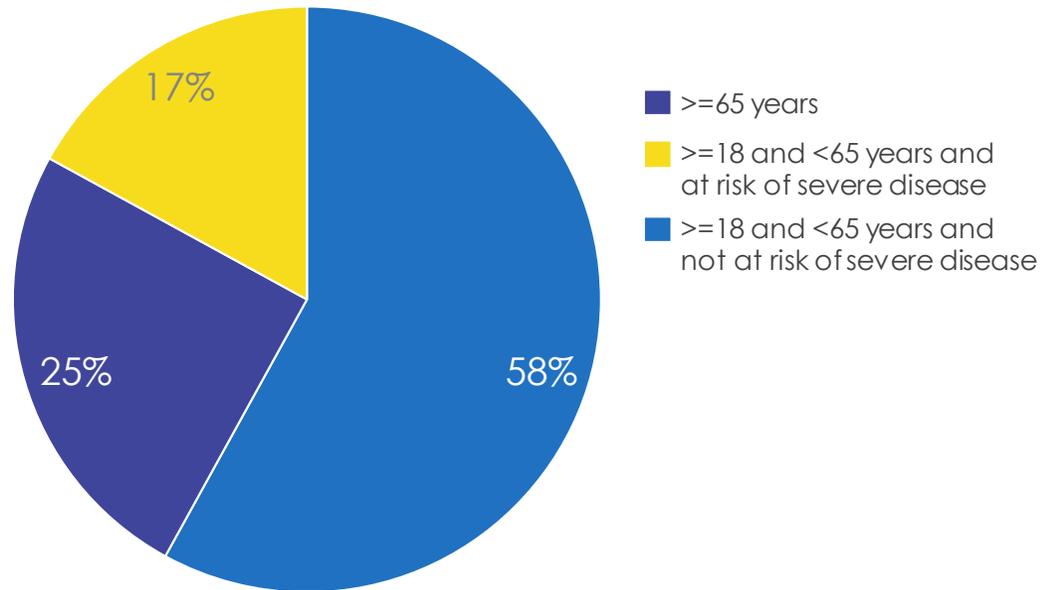
Gender distribution



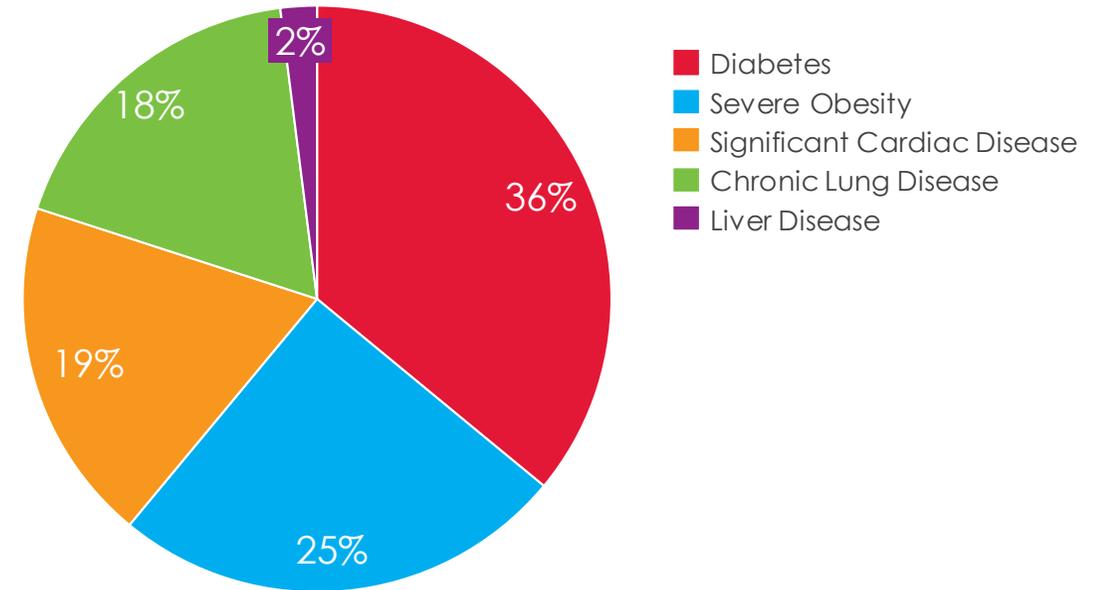
- 37% of the 30,000 participants are from communities of color, similar to diversity of the U.S. at large
- 6,000+ Hispanic/Latinx participants, 3,000+ Black/African American participants and 7,000+ participants over the age of 65

# COVE study successfully enrolled participants with risk factors for severe COVID-19 disease

Risk stratification

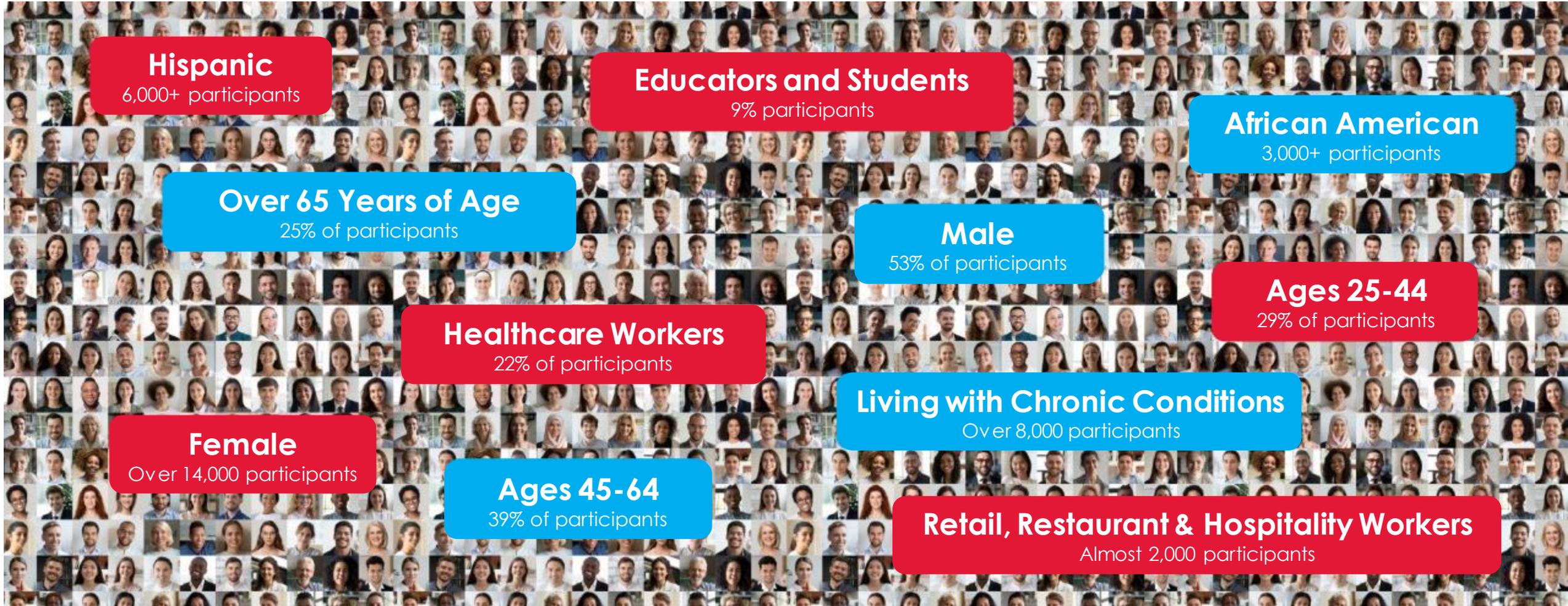


Comorbidities of at risk participants (all ages)



➤ 8,000+ participants who are living with chronic conditions

# A vaccine for everyone...find yourself in the COVE study



# Publicly announced supply agreements

*On track to supply between 500 million and 1 billion doses in 2021*

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## Deals signed

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- United States (100 million doses with option for additional 400 million doses)
- Japan (50 million doses)
- Canada (20 million doses with option for additional 36 million doses)
- Switzerland
- Israel
- Qatar
- Several countries not announced

## Deals in negotiation

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- European Union (advanced discussions for 80-160 million doses)
- COVAX (tiered pricing proposal)
- Many other countries

## Pricing of deals signed

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- Smaller volume agreements executed at \$32-37/dose
- US at ~\$25/dose for the first 100 million doses when including BARDA grant and potential performance-based payments



U.S. [press release](#); Japan [press release](#); Canada [press release](#); Switzerland [press release](#); Israel signs agreement with Moderna for potential COVID-19 vaccine ([Reuters](#)); Qatar [press release](#); European Union [press release](#)

# Ongoing regulatory engagements

## Rolling Submissions Ongoing

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- Canada
- United Kingdom
- Switzerland

## Other Regulatory Updates

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- Based on the interim safety and efficacy data, intend to submit for an Emergency Use Authorization (EUA) with the U.S. Food and Drug Administration (FDA) in the coming weeks
- Anticipates having the EUA informed by the final safety and efficacy data (with a median duration of at least 2 months)
- Confirmation of eligibility for submission of marketing authorization application to the European Medicines Agency (EMA)



Rolling submissions

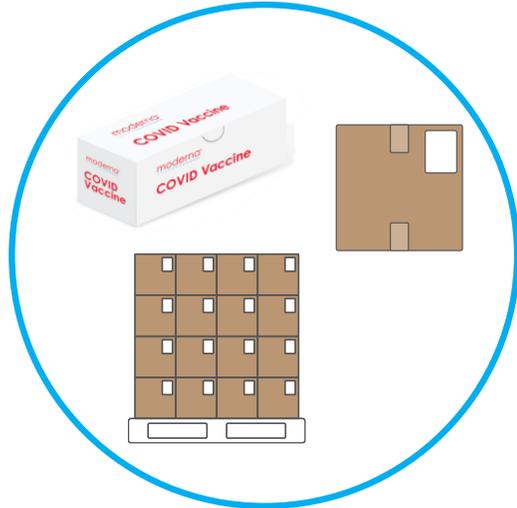


Ongoing interactions

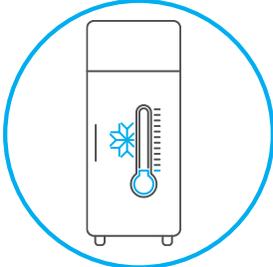


# Distribution to any immunization locations using existing infrastructure

## Storage Conditions\*

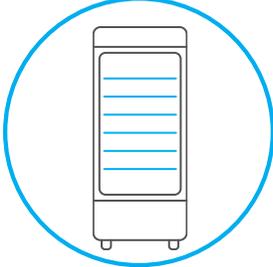


Ship any configuration using existing infrastructure



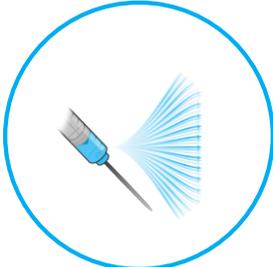
**Freezer: -20°C/-4°F for 6 months**

+



**Fridge: 2°-8°C/36°-46°F for up to 30 days**

+



**Room temperature: 12 hours post thaw**

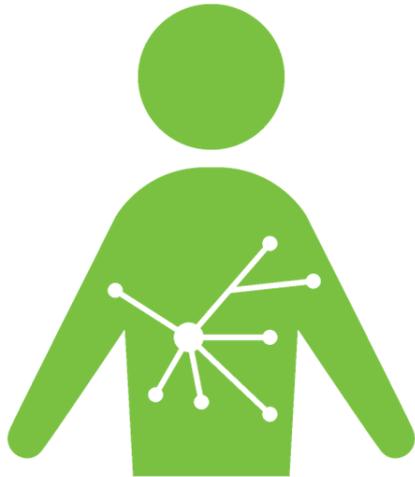
Flexible and adaptable supply chain

Uses standard existing vaccination infrastructure

No dilution required

Currently anticipate production of mRNA-1273 will be ~20 million doses by end of 2020

\*Shelf life is expected based on data available as of November 16, 2020; product characteristics subject to regulatory review and approval. 30 day storage at refrigerator temperatures of 2-8°C is within 6-month shelf life.



## ***Our mission***

*To deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.*