

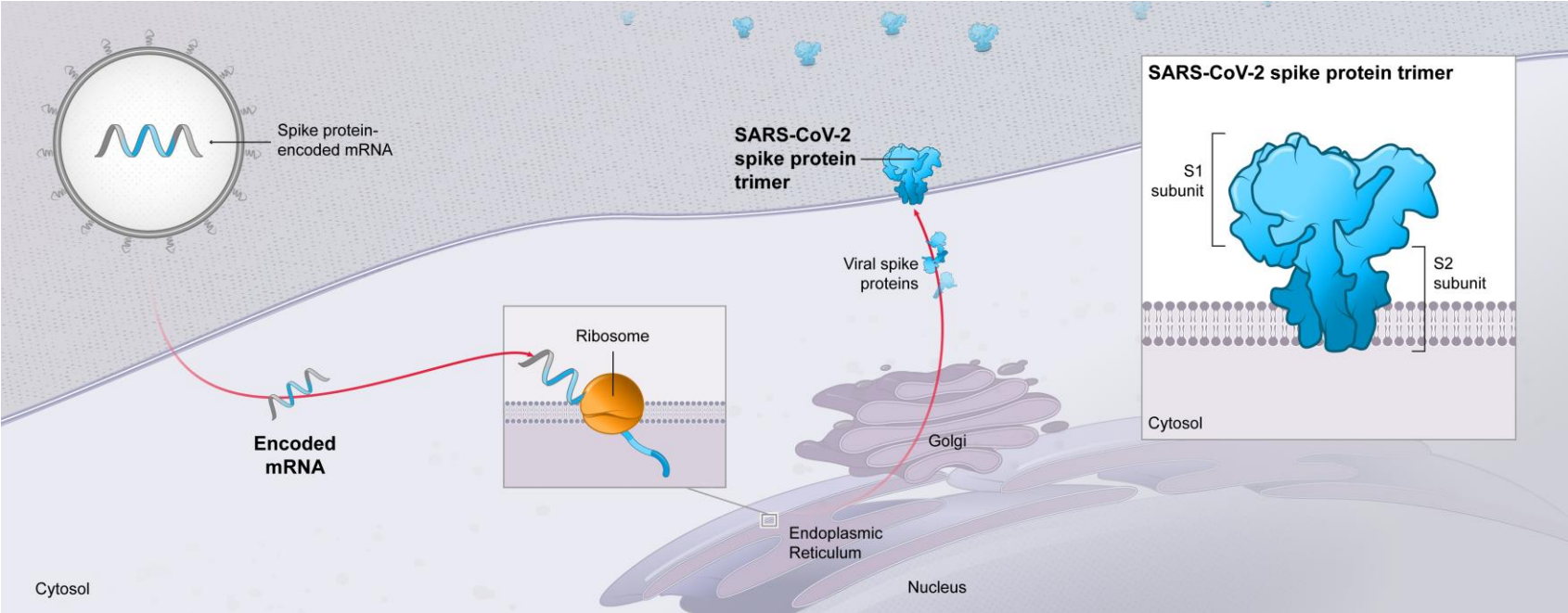
# Novel coronavirus (SARS-CoV-2) vaccine (mRNA-1273)

Last program update: May 29, 2020

Modality	ID #	Program		Preclinical development	Phase 1	Phase 2	Phase 3 and commercial	Moderna rights
 Prophylactic vaccines	mRNA-1273	Novel coronavirus (SARS-CoV-2) vaccine						Worldwide <i>BARDA funded</i>
	mRNA-1647	Cytomegalovirus (CMV) vaccine						Worldwide
	mRNA-1653	hMPV/PM3 vaccine		Phase 1 (healthy volunteers)	Phase 1b (Age de-escalation) Seropositives			Worldwide
	mRNA-1172/ Merck V172	Respiratory syncytial virus (RSV) vaccine						Merck to pay milestones and royalties
	mRNA-1777	Respiratory syncytial virus (RSV) vaccine						
	mRNA-1893	Zika vaccine						Worldwide <i>BARDA funded</i>
	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>

# SARS-CoV-2 vaccine (mRNA-1273)

Encodes for the full spike S protein



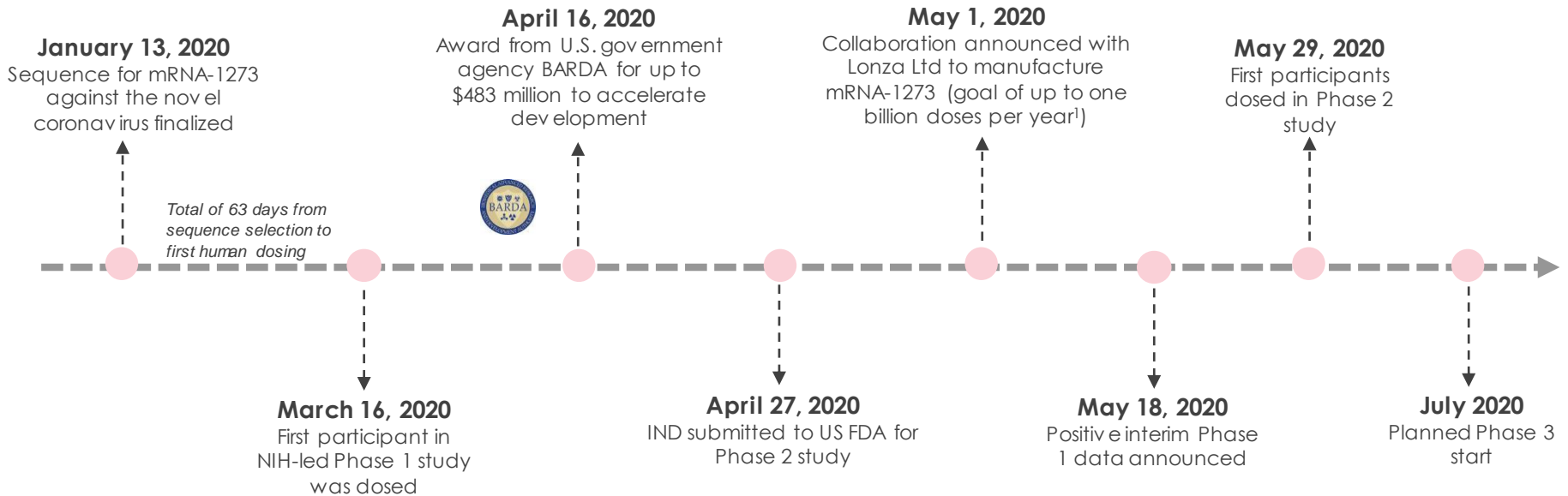
# SARS-CoV-2 vaccine (mRNA-1273) interim Phase 1 data

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- ✓ After two doses all participants evaluated to date across the 25 µg and 100 µg dose cohorts seroconverted with binding antibody levels at or above levels seen in convalescent sera
- ✓ mRNA-1273 elicited neutralizing antibody titer levels in all eight initial participants across the 25 µg and 100 µg dose cohorts, reaching or exceeding neutralizing antibody titers generally seen in convalescent sera
- ✓ mRNA-1273 was generally safe and well tolerated
- ✓ Anticipated dose for Phase 3 study between 25 µg and 100 µg; expected to start in July
- ✓ mRNA-1273 provided full protection against viral replication in the lungs in a mouse challenge model

# Accelerated research and development

## SARS-CoV-2 vaccine (mRNA-1273)



1. Assuming a dose of 50 µg

# SARS-CoV-2 vaccine (mRNA-1273)

## Phase 1 trial (run by the National Institutes of Health)

**Key objective:** To assess the safety, reactogenicity and immunogenicity of mRNA-1273

**Study design:** Phase 1, open-label dose ranging clinical trial in males and non-pregnant females, 18 to 55 years of age

- Forty-five subjects were enrolled into one of three cohorts (25, 100 and 250 µg)
- Subjects will receive 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:

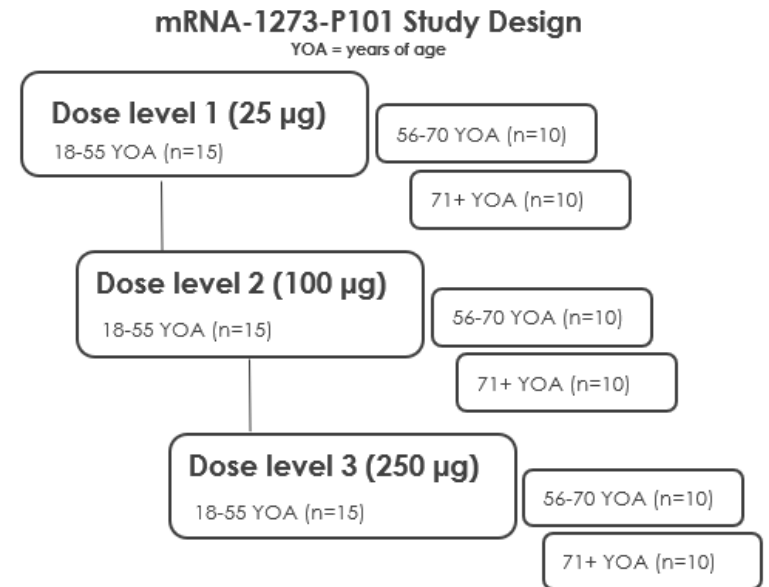
- Safety and reactogenicity of a 2-dose vaccination schedule of mRNA-1273, given 28 days apart, across 3 dosages in healthy adults

### Secondary endpoint:

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

### Trial progress/details:

- NIAID-led Phase 1 study of mRNA-1273 has completed enrollment of 3 dose cohorts (25 µg, 100 µg and 250 µg); expanded to an additional 6 cohorts of older adults and elderly adults; is being amended to include a 50 µg dose level cohort across each of the three age groups



# SARS-CoV-2 vaccine (mRNA-1273)

## Positive interim Phase 1 data

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- **Safety:** mRNA-1273 was generally safe and well tolerated, with a safety profile consistent with that seen in prior Moderna infectious disease vaccine clinical studies
  - The sole incidence of a grade 3 adverse event in the 25 µg and 100 µg dose cohorts was a single participant at 100 µg who experienced grade 3 erythema (redness) around the injection site
  - To date, the most notable adverse events were seen at the 250 µg dose level, comprising three participants with grade 3 systemic symptoms, only following the second dose
  - All adverse events have been transient and self-resolving. No grade 4 adverse events or serious adverse events have been reported
- **Immunogenicity data:** Currently available for the 25 µg and 100 µg dose level (ages 18-55) after two doses (day 43) and at the 250 µg level (ages 18-55) after one dose (day 29)
  - Dose dependent increases in immunogenicity were seen across the three dose levels, and between prime and boost within the 25 µg and 100 µg dose levels
  - All participants ages 18-55 (n=15 per cohort) across all three dose levels seroconverted by day 15 after a single dose
  - At day 43, two weeks following the second dose, at the 25 µg dose level (n=15), levels of binding antibodies were at the levels seen in convalescent sera (blood samples from people who have recovered from COVID-19) tested in the same assay
  - At day 43, at the 100 µg dose level (n=10), levels of binding antibodies significantly exceeded the levels seen in convalescent sera. Samples are not yet available for remaining participants
- **Neutralizing antibody data:** Available only for the first four participants in each of the 25 µg and 100 µg dose level cohorts
  - Consistent with the binding antibody data, mRNA-1273 vaccination elicited neutralizing antibodies in all eight of these participants, as measured by plaque reduction neutralization (PRNT) assays against live SARS-CoV-2
  - The levels of neutralizing antibodies at day 43 were at or above levels generally seen in convalescent sera

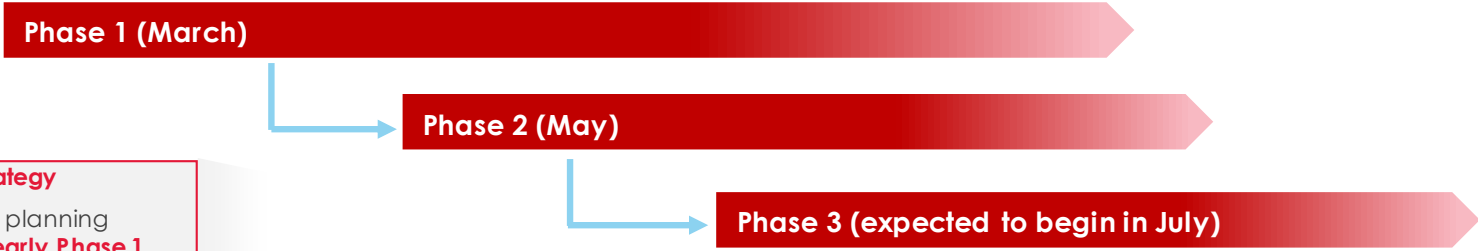
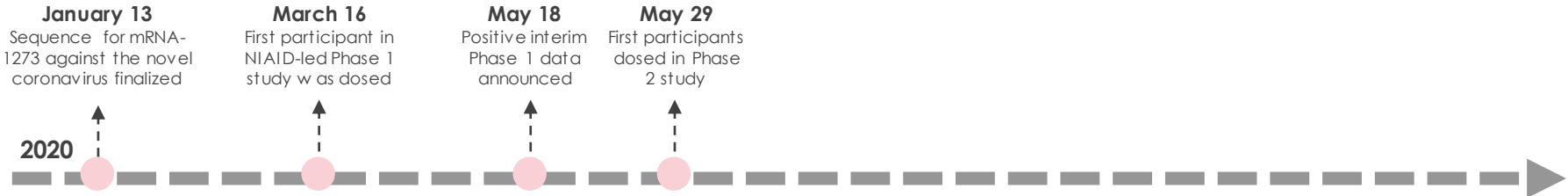
# SARS-CoV-2 vaccine (mRNA-1273)

## Preclinical results

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- Preclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available
- In this study, vaccination with mRNA-1273 prevented viral replication in the lungs of animals challenged with SARS-CoV-2
- Neutralizing titers in Phase 1 clinical trial participants at the 25 µg and 100 µg dose levels were consistent with neutralizing titers that were protective in the mouse challenge model

# SARS-CoV-2 vaccine (mRNA-1273) clinical development plan



**Accelerated strategy**

- Phase 2 study planning started after **early Phase 1 safety data** became available
- Phase 3 **expected to begin once early Phase 2 safety data** are available, subject to finalization of the clinical trial protocol



# Late stage development for SARS-CoV-2 vaccine (mRNA-1273)

## Phase 2 study

- Study will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart
- **Subject to receive placebo, a 50 µg or a 100 µg dose at both vaccinations; the Phase 2 study was amended based on the interim Phase 1 data<sup>1</sup>**
- 600 healthy participants; two cohorts of adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300)
- **First participants in each age cohort dosed (announced on May 29, 2020)**

**Finalizing protocol for Phase 3 study; expected to begin in July of 2020**

# Moderna and Lonza collaboration

Goal to enable manufacturing of up to one billion doses per year<sup>1</sup>

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Plan to establish **manufacturing suites** at Lonza's facilities in the U.S. and Switzerland

Technology transfer expected to begin in **June 2020**

First batches of mRNA-1273 expected to be manufactured at Lonza U.S. in **July 2020**

# Forward-looking statements

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