# COVID-19 vaccine (mRNA-1273)

*Last program update: May 6, 2021*

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<tr>
<th>Program</th>
<th>ID #</th>
<th>Preclinical development</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
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<td>mRNA-1273</td>
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<td>mRNA-1283</td>
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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. 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.
Moderna COVID-19 Vaccine: Authorized Use & Important Safety Information

Authorized Use in the United States:

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

Important Safety Information:

• Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

• Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

• Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

• The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

• Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine. Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

• Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfeeding infant or on milk production/excretion.

• There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

• Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

• Vaccination providers must complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.
Primary Efficacy Analysis in Phase 3 COVE Study for COVID-19 Vaccine Candidate

Primary efficacy analysis of the Phase 3 of mRNA-1273 indicates a vaccine efficacy of 94.1%

- Vaccine efficacy has been demonstrated at the first interim analysis with a total of 95 cases based on the pre-specified success criterion on efficacy
- Primary analysis on November 30th was based on 196 cases, of which 185 cases of COVID-19 were observed in the placebo group versus 11 cases observed in the mRNA-1273 group
- A secondary endpoint analyzed severe cases of COVID-19 and included 30 severe cases (as defined in the study protocol) in this analysis
  - All 30 cases occurred in the placebo group and none in the mRNA-1273 vaccinated group
  - There was one COVID-19-related death in the study to date, which occurred in the placebo group
- The 196 COVID-19 cases included 33 older adults (ages 65+) and 42 participants identifying as being from diverse communities (including 29 Hispanic or LatinX, 6 Black or African Americans, 4 Asian Americans and 3 multiracial participants)

mRNA-1273 continues to be generally well tolerated; no serious safety concerns identified to date

- Safety data continue to accrue and the study continues to be monitored by an independent, NIH-appointed Data Safety Monitoring Board (DSMB)

1. Data are subject to change based on ongoing analysis of further Phase 3 COVE study data and final analysis
2. Data updated as of November 30, 2020
## Phase 3 COVE Study Overview

- Placebo controlled
- Approximately 30,000 participants enrolled
- Participants received 100 µg or placebo
- Study objectives to demonstrate efficacy, safety and immunogenicity of mRNA-1273

## Phase 3 COVE Study Updates

- Demonstrated mRNA-1273 is well-tolerated with 94.1% vaccine efficacy against COVID-19 in the primary efficacy analysis
- 84% of the placebo participants have crossed over to the active arm
- Updated cases show continued strong efficacy, including greater than 90% against cases of COVID-19 and greater than 95% against severe cases of COVID-19, with approximately 6 months median follow-up post dose 2
We will be sharing updated data from our Phase 3 COVE study throughout the year.

- Efficacy against asymptomatic infection
- Genotyping data
- Durability data
- Correlate(s) of protection

Expecting multiple data points from the Phase 3 COVE Study

April 2021
Moderna COVID-19 Vaccine Population Expansion Studies

TeenCOVE
• Phase 2/3 study in adolescents ages 12-17 fully enrolled
• 3,000 participants enrolled in the U.S.
• Participants to receive placebo or 100 µg

KidCOVE
• Phase 2/3 study in pediatric population ages 6 months-11 years currently enrolling
• Expected to enroll 6,750 healthy pediatric participants in the U.S. and Canada
• Dose escalation study
  – Ages 2-11 to receive placebo, 50 µg or 100 µg
  – Ages six months–2 to receive placebo, 25 µg, 50 µg or 100 µg
  – Interim analysis to determine which dose will be used in Part 2

Japan study¹
• Placebo-controlled, Phase 1/2 study (TAK-919), led by Takeda, is fully enrolled
• 200 participants aged 20 years and older

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Our strategy for combating COVID-19

I. mRNA-1273: Moderna COVID-19 Vaccine
   - 50 μg of mRNA-1273

II. mRNA-1273.351: Variant-specific booster candidate based on the B.1.351 (variant first identified in the Republic of South Africa)
   - 20 μg of mRNA-1273.351 (N=20)
   - 50 μg of mRNA-1273.351 (N=20)

III. mRNA-1273.211: Multivalent booster candidate which combines mRNA-1273 and mRNA-1273.351 in a single vaccine
   - 50 μg of mRNA-1273.211 (N=20)

Phase 2 trial underway to evaluate three boosting strategies against variants of concern.
Additional manufacturing investments to respond to global need for mRNA COVID-19 vaccines in 2022 and beyond

### 2021 Supply

- Raised 2021 manufacturing supply forecast to between 800 million to 1 billion doses
- Aiming to produce 1 billion doses

### 2022 Supply

- Investments allow for a **doubling of drug substance production capacity** and an increase in formulation, fill and finish capacity in Europe
- An increase of 50% in drug substance production supply at Moderna’s facilities in the U.S.
- Global 2022 capacity increased to up to 3 billion doses for our COVID-19 vaccine (depending upon the dosage mix)
Best-in-class vaccine storage and distribution requirements among authorized mRNA vaccines

- Shipping is in standard freezers (-20°C) and 100 doses in carton to pallet(s) (237,600 doses/pallet)
- Storage is up to 6 months in a standard freezer and 4 weeks at refrigerated temperatures (2-8°C)
- Only authorized mRNA vaccine that does not require on-site dilution

Ongoing development data related to the current formulation could support a 3-month refrigerated (2-8°C) shelf life for the vaccine
Our commitment to provide access to our COVID-19 vaccine continues with our recently signed agreements for 2022 and beyond

**Recently signed deals for 2021, 2022 and beyond**

- **COVAX** (34 million doses in 2021 with option for up to additional 466 million doses in 2022)
- **Switzerland** (13.5 million doses and 7 million doses in 2022 and options for additional 7 million in 2022/23)
- **Israel** (6 million doses in 2021 and 5.2 million in 2022 with an option for 17 million in 2022/23)
- Brunei
- Botswana
- Zuellig Pharma

**Previously announced deals**

- United States (300 million doses with option for additional 200 million doses)
- European Union (310 million doses with option for additional 150 million doses in 2022)
- Japan (50 million doses)
- Canada (44 million doses)
- South Korea (40 million doses)
- Philippines, United Kingdom, Colombia, Taiwan, Qatar, Singapore
Moderna’s COVID-19 vaccine is protecting people in 37 countries already

102 million doses of Moderna COVID-19 vaccine shipped in 1Q 2021