



## Moderna Announces Additional Investments to Increase Global Supply for COVID-19 Vaccine to up to 3 Billion Doses in 2022

April 29, 2021

*Investments to increase supply globally, including doubling supply from Moderna's ex- U.S. supply chain*

*Supply also expected to benefit from shift to lower-dose product mix, including potential variant booster vaccines and pediatric primary vaccine doses*

*Company increases its 2021 supply forecast to between 800 million and 1 billion doses*

*Company also announced data supporting 3-month refrigerated (2-8°C) stable formulation*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 29, 2021-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced it is making new funding commitments to increase supply at its owned and partnered manufacturing facilities, which it expects will increase global 2022 capacity to up to 3 billion doses of its COVID-19 vaccine, depending upon the mix between the authorized Moderna COVID-19 Vaccine at the 100 µg dose level and potentially lower doses of the Company's variant booster candidates and pediatric vaccines, if authorized. The Company will use its cash balance to fund these investments.

These investments allow for a doubling of drug substance manufacturing at Lonza's (SIX: LONN) Switzerland-based facility, a more than doubling of formulation, fill and finish and drug substance manufacturing at Rovi's (BME: ROVI) Spain-based facility, as well as a 50% increase of drug substance at Moderna's facilities in the U.S. When completed, the investments will also result in an increase in safety stock of raw materials and finished product used to deliver committed volumes. The Company will begin making investments at its owned and partnered manufacturing facilities in 2021, with increased production from these investments expected to ramp up in late 2021 and early 2022. Today, the Company also raised its 2021 manufacturing supply forecast to between 800 million to 1 billion doses.

The increases announced today are in addition to the recently announced increases in formulation, fill and finish in the U.S. with [Catalent](#) and [Sanofi](#). In addition, Moderna is in advanced negotiations for other agreements.

"As we follow the rapid spread of SARS-CoV-2 variants of concern, we believe that there will continue to be significant need for our mRNA COVID-19 vaccine and our variant booster candidates into 2022 and 2023. We are hearing from governments that there is no technology that provides the high efficacy of mRNA vaccines and the speed necessary to adapt to variants, while allowing reliable scalability of manufacturing. Today we have announced that our investments in Europe, including Spain, France and Belgium, Switzerland, and the U.S. will allow us to deliver up to 3 billion doses in 2022, depending on the mix of product between primary series of vaccination and variant boosters," said Stéphane Bancel, Chief Executive Officer of Moderna. "We thank our manufacturing partners for their work and their commitment. Together with our partners, Moderna is committed to continuously developing best-in-class variant boosters so we can end this pandemic as fast as possible."

As shared at its [Vaccines Day presentation](#) on April 14, 2021, Moderna believes that this investment in increased supply is necessary due to an expected significant need for booster vaccinations in 2022 and beyond. The Company highlighted published studies predicting that waning immunity will impact vaccine efficacy within 12 months<sup>1</sup>, and published studies showing variants of concern have lower starting neutralizing antibody titers<sup>2</sup> and may lead to breakthrough infections among those already infected or vaccinated<sup>3</sup>, compounding the potential need for variant boosters in the coming years.

Also discussed at Vaccines Day, Moderna further believes that mRNA is the best-positioned technology platform to meet the global need for ongoing vaccinations against SARS-CoV-2. The Company's belief is based on the observations that mRNA vaccines have the highest published efficacy among authorized vaccines; the demonstrated ability of mRNA platforms to respond rapidly to the SARS-CoV-2 virus, including variants of concern; and the capability for mRNA technology to produce multi-valent vaccines. Moderna [announced](#) earlier this year that it is already testing SARS-CoV-2 variant vaccine and multivalent vaccine boosters in humans.

As Moderna observes results from its ongoing variants clinical trials and more fully develops its booster product strategy, it will be in a position to better estimate supply ranges for 2022, which will be based, in significant part, on product mix across single-dose boosters, primary (two-dose) vaccination series for adults, and primary (two-dose) series for the pediatric population, which may be at lower dose levels.

Moderna also announced today that ongoing development data related to the current formulation of the Moderna COVID-19 Vaccine (mRNA-1273) could support a 3-month refrigerated (2-8°C) shelf life for the vaccine in alternative formats to facilitate easier distribution to doctor's offices and other smaller settings if authorized. Currently, the Moderna COVID-19 Vaccine is approved for storage up to 1 month at refrigerated temperatures (2-8°C) and up to 7 months in a standard freezer (-20°C). The Moderna COVID-19 Vaccine is also the only authorized mRNA vaccine that does not require on-site dilution. The Company also announced that it is working on formulations of mRNA-1273 and a next generation vaccine (mRNA-1283) that it believes will extend refrigerated shelf life even further.

### About the Moderna COVID-19 Vaccine

The Moderna COVID-19 Vaccine is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein, which was co-developed by Moderna and investigators from the National Institute of Allergy and Infectious Diseases' (NIAID) Vaccine Research Center. The first clinical batch, which was funded by the Coalition for Epidemic Preparedness Innovations, was completed on February 7, 2020 and underwent analytical testing; it was shipped to the National Institutes of Health (NIH) on February 24, 2020, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of the Moderna COVID-19 Vaccine was dosed on March 16, 2020, 63 days from sequence selection to Phase 1 study dosing. On May 12, 2020, the U.S. FDA granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, 2020, the first participants in each age cohort were dosed in the Phase 2 study of the vaccine. On July 8, 2020, the Phase 2 study completed enrollment.

Results from the second interim analysis of the NIH-led Phase 1 study of the Moderna COVID-19 Vaccine in the 56-70 and 71+ age groups were published on September 29, 2020 in *The New England Journal of Medicine*. On November 30, 2020, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On November 30, 2020, the Company also announced that it filed for Emergency Use Authorization with the U.S. FDA and a Conditional Marketing Authorization (CMA) application with the European Medicines Agency. On December 18, 2020, the U.S. FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. Moderna has also received authorization for its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar and Taiwan. Additional authorizations are currently under review in other countries and by the World Health Organization.

Preclinical data on the Company's variant-specific booster vaccine candidates have been submitted as a preprint to [bioRxiv](#) and will be submitted for peer-reviewed publication. These variant-specific vaccine candidates include mRNA-1273.351, which is more specifically targeted against the SARS-CoV-2 variant known as B.1.351 first identified in the Republic of South Africa, and a multivalent booster candidate, mRNA-1273.211, which combines mRNA-1273 (Moderna's authorized vaccine against ancestral strains) and mRNA-1273.351 in a single vaccine. The Company's Phase 2 study to evaluate three [approaches to boosting](#) is ongoing.

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) is supporting the continued research and development of the Company's COVID-19 vaccine development efforts with federal funding under contract no. 75A50120C00034. BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract. The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

## AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

## 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/clinical-considerations/managing-anaphylaxis.html>).
- 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.
- 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 breastfed 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.

Click for [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) and Full EUA Prescribing Information](#) for more information.

## About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and

auto-immune diseases. Today, 24 development programs are underway across these therapeutic areas, with 13 programs having entered the clinic. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit [www.modernatx.com](http://www.modernatx.com).

## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the Company's development of a vaccine (mRNA-1273) to protect against the SARS-CoV-2 virus, which causes COVID-19; investments to increase the supply of the Moderna COVID-19 Vaccine and the anticipated number of doses that may be produced in the future and the timing for such production; the Company's vaccine supply forecasts for 2021 and 2022; the advantages of an mRNA-based platform for the production of vaccines; the ability of the Moderna COVID-19 Vaccine to protect against COVID-19 over time; the Company's ability to develop vaccines against variants of the SARS-CoV-2 virus and the protection conferred by those variant-specific vaccines; the need for booster vaccines against the SARS-CoV-2 virus and its variants and the potential dosages for those booster vaccines; the conduct of clinical studies for variant-specific boosters; the duration of protection against SARS-CoV-2 from existing vaccines; and the conditions under which the Moderna COVID-19 Vaccine can be shipped and stored, and efforts to develop versions of the Company's vaccines that are stable at refrigerated temperatures. 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 press release 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 safety, tolerability and efficacy profile of the Moderna COVID-19 Vaccine observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; the Moderna COVID-19 Vaccine may prove less effective against variants of the SARS-CoV-2 virus, or the Company may be unsuccessful in developing future versions of its vaccine against these variants; 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; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or additional emergency use authorization applications may be filed in various jurisdictions and ultimately approved by regulatory authorities; 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 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](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 press release 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.

<sup>1</sup> <https://www.medrxiv.org/content/10.1101/2021.03.09.21252641v1.full.pdf>

<sup>2</sup> <https://www.biorxiv.org/content/10.1101/2021.01.25.427948v1>

<sup>3</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa2105000>

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