Moderna Announces Additional Capital Investments to Increase Global Manufacturing Capacity for COVID-19 Vaccine

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New capital investments at Moderna's manufacturing facilities expected to increase 2022 capacity to approximately 1.4 billion doses at the 100 µg dose

Moderna also increases its 2021 base plan to 700 million doses and is working to supply up to 1 billion doses in 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 24, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, announces it is making new capital investments to increase capacity at its owned and partnered manufacturing facilities, which it expects will increase global 2022 capacity to approximately 1.4 billion doses of its COVID-19 vaccine, assuming a 100 µg dose. The investments will enable additional production of the current Moderna COVID-19 Vaccine and provide flexibility in addressing production of potential vaccine boosters that may be needed to address emerging variants of SARS-CoV-2.

The Company has already begun adding this capacity at its owned and partnered manufacturing facilities. Given a six- to nine-month timeframe to add capacity and an additional timeframe to permit regulatory validation and ramp-up, it is estimated that up to 12 months may be necessary before the additional production is available.

"We believe from our discussions with governments around the world that there will continue to be significant demand for our COVID-19 vaccine and we now are committed to materially increasing our manufacturing capacity. Because of the high efficacy of our COVID-19 vaccine and our ability to quickly develop variant vaccines to help boost the immune system of vaccinees, there is increased demand. We are investing in this additional capacity to help us increase production and allow for flexibility in manufacturing potential vaccine boosters to address emerging variants of the virus," said Stephane Bancel, Chief Executive Officer of Moderna. "Today we also announced our strategy around clinical testing of different booster vaccines. We expect our additional capital investments to drive our capacity to 1.4 billion doses for 2022, assuming the current 100 µg dose. If our variant vaccine booster requires a lower dose, such as 50 µg, we could have more than 2 billion doses of capacity for 2022."

The 2022 *capacity* of up to 1.4 billion doses reflects an assumption of a 100 µg dose. The 2022 *output* will depend on the dose of the booster. The Company plans to study a dose range of 50 µg and lower for variant-based boosters and an additional booster of mRNA-1273. If the effective dose for a booster is 50 µg, then the 2022 supply could be significantly higher than 1.4 billion doses. The total 2022 supply will depend on the mix between the authorized COVID-19 Vaccine at 100 µg and the dose level authorized for a booster. In the event that the Company dedicates its entire 2022 capacity to a 50 µg boost, the Company could supply up to 2.8 billion doses in fiscal year 2022. The maximum output will be determined as the Company more fully develops its booster product strategy.

Moderna also announces it is increasing its base plan for 2021 manufacturing from 600 million doses to 700 million doses globally. Moderna is exploring other approaches to potentially improve throughput and is working to further optimize its operations to potentially deliver up to 1 billion doses in fiscal year 2021.

The Company has shipped approximately 60 million doses globally including approximately 55 million doses shipped to the U.S. Government to date and the first approximately 4 million doses shipped from its ex-U.S. supply chain. This ex-U.S. supply chain was established one quarter behind the U.S. supply chain and is in the process of ramping up.

An additional approximately 33 million doses have been produced in the U.S. and are filled in vials and in the final stages of production and testing before release. Moderna expects to complete delivery of the first 100 million doses to the U.S. Government by the end of the first quarter 2021, the second 100 million doses by the end of May 2021 and the third 100 million doses by the end of July 2021.

Since the end of 2020, the Company has doubled its monthly deliveries to the U.S. government, and is working to double them again by April to more than 40 million doses per month. As the Company works to meet these goals, it is continually learning and working closely with its partners and the federal government to identify ways to address bottlenecks and accelerate production. For example, one of the recently identified constraints on the production process has been the capacity of the fill-and-finish process. To reduce this constraint, Moderna studied the possibility of adding more doses to each vial of vaccine. Doing so would improve output because it allows complete manufacturing to run more quickly and it reduces the need for consumable materials that are in high demand. The FDA has provided positive feedback on this proposal, and the Company is pursuing a plan that may allow up to 15 doses to be drawn from each vial. This will allow the Company to produce and deliver additional doses more quickly. Moderna will continue to collaborate with its manufacturing partners and the federal government to increase the efficiency of its production process without compromising quality or safety.

The Moderna COVID-19 Vaccine received Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) on December 18, 2020 and Moderna began supplying to the government shortly thereafter. The U.S. Government has agreed to purchase 300 million doses of the Moderna COVID-19 Vaccine, and has options to purchase 200 million additional doses.

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 Disease's (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 Food and Drug Administration granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, 2020, the first participants in each age cohort: adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300) were dosed in the Phase

2 study of the vaccine. On July 8, 2020, the Phase 2 study completed enrolment. 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 July 28, 2020, results from a non-human primate preclinical viral challenge study evaluating the vaccine were published in The New England Journal of Medicine. On July 14, 2020, an interim analysis of the original cohorts in the NIH-led Phase 1 study of the vaccine was published 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 3, 2020, a letter to the editor was published in The New England Journal of Medicine reporting that participants in the Phase 1 study of the Moderna COVID-19 Vaccine retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination). 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 and Qatar. Additional authorizations are currently under review in other countries and by the World Health Organization.

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 mRNA-1273 with $955 million in 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. Moderna COVID-19 Vaccine is investigational and not approved by FDA.

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.
- 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.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, 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.

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 investments and initiatives to increase supply and manufacturing capacity for the Moderna COVID-19 Vaccine; the timeline for such capacity increases; regulatory approvals for expanding manufacturing capacity; future demand for the Moderna COVID-19 Vaccine; the efficacy of the Moderna COVID-19 Vaccine; the Company's ability to quickly develop effective vaccines in response to variants of the SARS-CoV-2 virus; the dosage for boosts of the Moderna COVID-19 Vaccine or vaccines developed in response to variants; the impact of different dosage levels on supply capabilities; and the potential for the U.S. government to exercise its option to purchase additional doses of the Moderna COVID-19 Vaccine. 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 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 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.

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