# Moderna Provides COVID-19 Vaccine Supply Update

January 4, 2021

*Raises lower end of global manufacturing plan for 2021 from 500 million doses previously to 600 million doses*

*Continues to invest and hire in order to deliver up to 1 billion doses in 2021*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 4, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today provided a supply update for the Moderna COVID-19 Vaccine, increasing its base-case global production estimate from 500 to 600 million doses for 2021. Moderna said it is continuing to invest and add staff to build up to potentially 1 billion doses for 2021.

The Company said it expects about 100 million doses to be available in the United States by the end of the first quarter of 2021, with 200 million doses total available by the end of the second quarter. Moderna reported that approximately 18 million doses have been supplied to the U.S. Government to date. The 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. Additional vaccine doses have also been supplied to the Canadian government following authorization by Health Canada's Interim Order on December 23, 2020.

“Our effectiveness in providing early supply to the U.S. and Canadian governments and our ability to increase baseline production estimates for 2021 are both signals that our scale up of mRNA vaccine production is a success,” said Juan Andres, Chief Technical Operations and Quality Officer at Moderna. “I want to thank the many private and government collaborators, contractors and the hundreds of Moderna staff who have been working thoughtfully and tirelessly to accomplish this.”

Moderna is partnered with Lonza Ltd. for production inside and outside the United States. Fill-finish services are provided by Catalent Inc. in the U.S., and by ROVI and Recipharm outside the U.S. The U.S. Government has agreed to purchase 200 million doses of the Moderna COVID-19 Vaccine with options for potential purchase of 300 million additional doses. The Canadian Government has agreed to purchase 40 million 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 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, 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, 63 days from sequence selection to Phase 1 study dosing. On May 12, the FDA granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, 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 mRNA-1273. On July 8, 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 in *The New England Journal of Medicine*. On July 28, 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, 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, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On November 30, the Company also announced that it filed for Emergency Use Authorization with the U.S. FDA and a Conditional Marketing Authorization (CMA) with the European Medicines Agency. On December 3, 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) and on December 30, interim safety and primary efficacy results from the Phase 3 trial were published in *The New England Journal of Medicine*. On December 18, 2020, the FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older.

**Authorized Use**

The Moderna COVID-19 Vaccine has been authorized for emergency use in the U.S. by the FDA 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 and has been authorized by Health Canada for the immunization of Canadians 18 years of age and older under an Interim Order. Moderna has submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

**About Moderna**

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body’s cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. The company’s platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune and inflammatory diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and BARDA. 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 regarding: the Company's development of a vaccine against the novel coronavirus, and the timeline and scale for manufacturing and distribution 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; 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 emergency use authorization applications may be filed 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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**Media:**
Colleen Hussey
Director, Corporate Communications
617-335-1374
Colleen.Hussey@modernatx.com

**Investors:**
Lavina Talukdar
Senior Vice President & Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.