



## European Commission Authorizes COVID-19 Vaccine Moderna in Europe

January 6, 2021

*Authorization follows European Medicines Agency recommendation of COVID-19 Vaccine Moderna*

*European Commission has secured 160 million doses; first deliveries to countries will begin next week*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2021-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the European Commission has granted a conditional marketing authorization (CMA) for COVID-19 Vaccine Moderna, allowing vaccination programs using the Moderna vaccine to be rolled out across the European Union. The authorization is based upon the recommendation of the European Medicines Agency (EMA) for use of the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

"I want to thank the European Commission for its engagement and endorsement and the EMA for its recommendation, which is another significant moment in our company's history," said Stéphane Bancel, Chief Executive Officer of Moderna. "The EMA and the Committee for Medicinal Products for Human Use reviewers, working over the holidays, provided a thorough review and comprehensive guidance as we worked together to achieve this authorization. I am proud of the role Moderna has been able to play globally in helping to address this pandemic."

The European Union is the fourth jurisdiction to authorize Moderna's COVID-19 vaccine, following the United States on December 18, 2020, Canada on December 23, 2020 and Israel on January 4, 2021. Additional authorizations are currently under review in Singapore, Switzerland and the United Kingdom.

On December 18, the EMA [exercised](#) its option to increase its confirmed order commitment by 80 million doses of Moderna's vaccine against COVID-19, bringing its confirmed order commitment to 160 million doses. The first deliveries of COVID-19 Vaccine Moderna to European countries from Moderna's dedicated non- U.S. supply chain are expected to begin next week.

The EMA's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for COVID-19 Vaccine Moderna based on the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study [announced](#) on November 30.

To learn more about Moderna's work on the Moderna COVID-19 Vaccine, visit [www.modernatx.com/COVID19](http://www.modernatx.com/COVID19).

### About the COVID-19 Vaccine Moderna

The COVID-19 Vaccine Moderna (referred to in the U.S. as 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 NIAID's 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 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 U.S Food and Drug Administration 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 the vaccine. On July 8, 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 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) application 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). On December 18, 2020, the U.S. FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older. On December 23, 2020, Health Canada [authorized](#) Moderna's vaccine against COVID-19 for the immunization of people 18 years of age and older under an Interim Order. On January 4, 2021, Israel's Ministry of Health (MOH) authorized the importation of the COVID-19 Vaccine Moderna in Israel.

### Authorized Use

The COVID-19 Vaccine Moderna has been granted a Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency, which authorizes the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

### 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](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 regarding: the Company's development of a vaccine against the novel coronavirus, and plans for the supply and distribution of the Moderna COVID-19 Vaccine to Member States of the European Union. 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](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.

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