



## Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization

November 30, 2020

*Primary efficacy analysis of the Phase 3 COVE study of mRNA-1273 involving 30,000 participants included 196 cases of COVID-19, of which 30 cases were severe*

*Vaccine efficacy against COVID-19 was 94.1%; vaccine efficacy against severe COVID-19 was 100%*

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

*Phase 3 COVE Study has exceeded 2 months of median follow-up post vaccination as required by the U.S. FDA for Emergency Use Authorization (EUA)*

*Moderna plans today to request EUA from the U.S. FDA, to apply for a conditional marketing authorization with the European Medicines Agency (EMA) and to progress with the rolling reviews, which have already been initiated with international regulatory agencies*

*FDA has told Company to expect VRBPAC meeting for mRNA-1273 likely on December 17, 2020*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 30, 2020-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that the primary efficacy analysis of the Phase 3 study of mRNA-1273 conducted on 196 cases confirms the high efficacy observed at the first interim analysis. The data analysis indicates a vaccine efficacy of 94.1%. Safety data continue to accrue and the study continues to be monitored by an independent, NIH-appointed Data Safety Monitoring Board (DSMB). The Company also announced that today, Moderna plans to request an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and conditional approval from the European Medicines Agency (EMA). The Phase 3 study, known as the COVE study, enrolled more than 30,000 participants in the U.S. and is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

The primary endpoint of the Phase 3 COVE study is based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine. 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. Today's primary analysis 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, resulting in a point estimate of vaccine efficacy of 94.1%. 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.

Efficacy was consistent across age, race and ethnicity, and gender demographics. 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).

The safety profile of the Phase 3 study of mRNA-1273 was [previously described](#) on November 16. A continuous review of safety data is ongoing and no new serious safety concerns have been identified by the Company. Based on prior analysis, the most common solicited adverse reactions included injection site pain, fatigue, myalgia, arthralgia, headache, and erythema/redness at the injection site. Solicited adverse reactions increased in frequency and severity in the mRNA-1273 group after the second dose.

The Company will submit data from the Phase 3 COVE study to a peer-reviewed publication.

"This positive primary analysis confirms the ability of our vaccine to prevent COVID-19 disease with 94.1% efficacy and importantly, the ability to prevent severe COVID-19 disease. We believe that our vaccine will provide a new and powerful tool that may change the course of this pandemic and help prevent severe disease, hospitalizations and death," said Stéphane Bancel, Chief Executive Officer of Moderna. "I want to thank the thousands of participants in our Phase 1, Phase 2 and Phase 3 studies, as well as the staff at clinical trial sites who have been on the front lines of the fight against the virus. I would again like to thank our partners at NIH, NIAID, BARDA and Operation Warp Speed who have helped us advance the clinical development of mRNA-1273. Finally, I want to thank the Moderna team and our suppliers and partners for their tireless work on the research, development and manufacturing of our vaccine. We will file today for an Emergency Use Authorization from the FDA and continue forging ahead with the rolling reviews that have already been initiated with several regulatory agencies around the globe."

Today, Moderna will submit for an EUA with the U.S. FDA and an application for Conditional Marketing Authorization (CMA) with the European Medicines Agency. The Company has already initiated the rolling review process with the EMA, Health Canada, SwissMedic, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), Ministry of Health in Israel, and Health Sciences Authority in Singapore and intends to seek Prequalification (PQ) and/or Emergency Use Listing (EUL) with the World Health Organization (WHO).

Additionally, Moderna announced that the FDA's [Vaccines and Related Biological Products Advisory Committee](#) (VRBPAC) meeting to review the safety and efficacy data package for mRNA-1273 will likely be scheduled for Thursday, December 17. The Company expects that the U.S. Centers for Disease Control and Prevention (CDC) [Advisory Committee on Immunization Practices](#) (ACIP) will make a recommendation on immunization priorities. The Company anticipates that the shipping of mRNA-1273 to designated distribution points throughout the U.S. will occur shortly after an Emergency Use Authorization is granted.

Moderna is working with the U.S. CDC, Operation Warp Speed and McKesson (NYSE: MCK), a COVID-19 vaccine distributor contracted by the U.S.

government, as well as global stakeholders to be prepared for distribution of mRNA-1273, in the event that it receives an EUA and similar global authorizations and approvals. By the end of 2020, the Company expects to have approximately 20 million doses of mRNA-1273 available in the U.S. The Company remains on track to manufacture 500 million to 1 billion doses globally in 2021. On November 10, the American Medical Association (AMA) issued a [Current Procedural Terminology \(CPT\) code](#) to report vaccination with mRNA-1273 (code: 91301). Moderna [recently announced](#) further progress towards ensuring the distribution, storage and handling of the vaccine can be done using existing infrastructure.

To learn more about Moderna's work on mRNA-1273, visit [www.modernatx.com/COVID19](http://www.modernatx.com/COVID19).

### **About the Phase 3 COVE Study**

The Phase 3 COVE trial is a randomized, 1:1 placebo-controlled study testing mRNA-1273 at the 100 µg dose level in 30,000 participants in the U.S., ages 18 and older. The primary endpoint is the prevention of symptomatic COVID-19 disease. Key secondary endpoints include prevention of severe COVID-19 disease and prevention of infection by SARS-CoV-2. The trial will continue to accrue additional data relevant to safety and efficacy even after an EUA is submitted. The final estimates of vaccine efficacy for both primary and secondary endpoints will depend on the totality of data that will accumulate to inform the final analysis. Moderna worked closely with BARDA and the NIH, including NIAID's COVID-19 Prevention Network ( [CoVPN](#)), to conduct the Phase 3 COVE study under Operation Warp Speed. Moderna's partner PPD (Nasdaq: [PPD](#)), a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services, has also been essential to the successful execution of the COVE study.

The Phase 3 COVE study was designed in collaboration with the FDA and NIH to evaluate Americans at risk of severe COVID-19 disease and [completed enrollment](#) of more than 30,000 participants ages 18 and older in the U.S. on October 22, including those at high risk of severe complications of COVID-19 disease. The COVE study includes more than 7,000 Americans over the age of 65. It also includes more than 5,000 Americans who are under the age of 65 but have high-risk chronic diseases that put them at increased risk of severe COVID-19, such as diabetes, severe obesity and cardiac disease. These medically high-risk groups represent 42% of the total participants in the Phase 3 COVE study. The study also included communities that have historically been under-represented in clinical research and have been disproportionately impacted by COVID-19. The study includes more than 11,000 participants from communities of color, representing 37% of the study population, which is similar to the diversity of the U.S. at large. This includes more than 6,000 participants who identify as Hispanic or LatinX, and more than 3,000 participants who identify as Black or African American.

### **About mRNA-1273**

mRNA-1273 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 mRNA-1273 was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. On May 12, the FDA granted mRNA-1273 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 mRNA-1273 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 mRNA-1273 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 mRNA-1273 was [published](#) in *The New England Journal of Medicine*. mRNA-1273 currently is not approved for use by any regulatory body.

BARDA 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 provide up to \$1.525 billion to purchase supply of mRNA-1273 under U.S. Department of Defense Contract No. W911QY-20-C-0100.

### **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 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 Company's anticipated production of mRNA-1273, and the timing of the initial shipments 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 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 mRNA-1273 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 mRNA-1273; 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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**Media:**

Colleen Hussey  
Director, Corporate Communications  
617-335-1374  
[Colleen.Hussey@modernatx.com](mailto:Colleen.Hussey@modernatx.com)

**Investors:**

Lavina Talukdar  
Senior Vice President & Head of Investor Relations  
617-209-5834  
[Lavina.Talukdar@modernatx.com](mailto:Lavina.Talukdar@modernatx.com)

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