



## Moderna Provides Updates on the Clinical Development and Production of Its COVID-19 Vaccine Candidate

December 3, 2020

*Interim durability data from NIH-led Phase 1 study of mRNA-1273 published as letter to the editor in NEJM; at day 119, 3 months post-second 100 µg dose, binding and neutralizing antibody titers remain high in all participants; results consistent across all age groups (18-55, 56-70 and 71+)*

*Company reaffirms expectation to have 20 million doses available in U.S. by the end of 2020*

*Company expects to have between 100 million and 125 million doses available globally in the first quarter of 2021*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 3, 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 provided an update on the clinical development and production of mRNA-1273, its vaccine candidate against COVID-19.

### Interim Durability Data from NIH-led Phase 1 Study of mRNA-1273

Today, a letter to the editor was [published](#) in the *New England Journal of Medicine* reporting that participants in the Phase 1 study of mRNA-1273, its COVID-19 vaccine candidate, retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination). The study was led by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Author Alicia T. Widge M.D. of Vaccine Research Center, NIAID, NIH and others summarized that “mRNA-1273 produced high levels of binding and neutralizing antibodies that declined slightly over time, as expected, but they remained elevated in all participants three months after the booster vaccination.” These results were consistent across all age cohorts (18-55, 56-70 and 71+). The authors continued, “Although correlates of protection against SARS-CoV-2 infection in humans are not yet established, these results show that despite a slight expected decline in titers of binding and neutralizing antibodies, mRNA-1273 has the potential to provide durable humoral immunity.” They also reported that, “No serious adverse events were noted in the trial, no prespecified trial-halting rules were met, and no new adverse events that were considered by the investigators to be related to the vaccine occurred after day 57.” The full letter and associated data are available [here](#).

“These interim Phase 1 data suggests that mRNA-1273, our COVID-19 vaccine candidate can generate durable neutralizing antibodies across all age groups including in older and elderly adults. Live virus and pseudovirus assay geometric mean titers (GMTs) remain high in the first months following vaccination,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer of Moderna. “These data give us further optimism to expect that the high level of efficacy recently demonstrated by mRNA-1273 to prevent COVID-19 disease will be durable.”

### Production Update

Today, Moderna re-affirmed its expectation of having approximately 20 million doses available in the U.S. by the end of 2020. Additionally, the Company expects to have between 100 million and 125 million doses available globally in the first quarter of 2021, with 85-100 million of those available in the U.S. and 15-25 million of those available outside of the U.S. These expected first quarter doses are inclusive within the 500 million to up to 1 billion doses that the Company expects to manufacture globally in 2021.

Today’s announcement follows the Company’s November 30 [announcement](#) that the primary efficacy analysis of the Phase 3 study of mRNA-1273 conducted on 196 cases confirmed 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). 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. Also on November 30, Moderna submitted a request for 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 NIAID 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.

### 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 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*. A summary of the company’s work to date on COVID-19 can be found [here](#).

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 committed up to \$1.525 billion to purchase supply of mRNA-1273 under U.S. Department

## 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 potential vaccine (mRNA-1273) against the novel coronavirus, statements concerning the potential for mRNA-1273 to generate binding and neutralizing antibodies and the durability of those antibodies over time in different age cohorts, the potential for adverse side effects from mRNA-1273, the conduct of the Phase 3 trial for mRNA-1273 and the review of safety and efficacy data, the U.S. government's potential purchases of mRNA-1273, and plans for the manufacture of mRNA-1273 and the timing and scale of anticipated production and geographic distribution. 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 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20201203006097/en/): <https://www.businesswire.com/news/home/20201203006097/en/>

### 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)

Source: Moderna, Inc.