



Moderna Has Completed Case Accrual for First Planned Interim Analysis of its mRNA Vaccine Against COVID-19 (mRNA-1273)

November 11, 2020

Acceleration in rate of COVID-19 disease across trial sites; Company expects more than 53 cases will be submitted to Data Safety Monitoring Board for the first interim analysis

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 11, 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 it has completed case accrual for the first interim analysis of the Phase 3 COVE study of mRNA-1273, its COVID-19 vaccine candidate.

Moderna has seen a significant increase in the rate of case identification across sites in the last week. As a result, the Company expects the first interim analysis will include substantially more than 53 cases, the targeted trigger point for the analysis. The data on these cases is being prepared for submission to the independent Data Safety Monitoring Board (DSMB) for analysis and recommendation. Moderna remains blinded to whether these participants received vaccine or placebo.

On October 22, the Phase 3 COVE study of mRNA-1273 [completed enrollment](#) of 30,000 participants in the U.S. The randomized, 1:1 placebo-controlled Phase 3 trial is studying mRNA-1273 at the 100 µg dose. 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 [ClinicalTrials.gov](#) identifier is NCT04470427.

The Phase 3 study was designed in collaboration with the FDA and NIH to evaluate Americans at the highest risk of severe COVID-19 disease and included more than 7,000 Americans over the age of 65. It also included 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. Moderna also worked to develop a vaccine for everyone, including communities that have historically been under-represented in clinical research and are disproportionately impacted by COVID-19. The study included more than 11,000 participants from communities of color, representing 37% of the study population and similar to the diversity of the U.S. at large. This included 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 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 of Defense Contract No. W911QY-20-C-0100.

Moderna has said it expects to be able to produce about 20 million doses of mRNA-1273 in 2020 and from 500 million up to one billion doses worldwide in 2021.

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, the number of cases to be included in the first interim analysis of the Phase 3 COVE Study of mRNA-1273, the U.S. government's potential purchases of mRNA-1273, and the anticipated manufacturing and supply 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: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved, and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; 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; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the fact that the safety and efficacy of mRNA-1273 has not yet been established; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and 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.