



Moderna Completes Enrollment of Phase 3 COVE Study of mRNA Vaccine Against COVID-19 (mRNA-1273)

October 22, 2020

Moderna to make statement at today's FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting

Moderna thanks PPD, its CRO partner, for the successful execution of COVE Study enrollment

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 22, 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 enrollment of 30,000 participants for the Phase 3 COVE study of mRNA-1273, its vaccine candidate against COVID-19, being conducted in collaboration with 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. To date, more than 25,650 participants have received their second vaccination. Moderna will determine whether to submit a dossier to FDA requesting Emergency Use Authorization based on an assessment of whether the potential benefit of the vaccine outweighs the potential risks once the 2 months of median safety follow-up have accrued.

The Company separately shared its statement at today's U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) [meeting](#).

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 to date of the COVE study. PPD also supported the Phase 2 study of mRNA-1273.

The Phase 3 COVE study was designed in collaboration with the FDA and NIH to evaluate Americans at the highest risk of severe COVID-19 disease. As of today, 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.

Moderna has 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. In early September, the Company announced a slowing of enrollment to ensure the representation of those communities of color in COVE. Today, Moderna is pleased to share that the study includes 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 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. A summary of demographic details can be found in [the slides issued](#) with this press release.

"Completing enrollment of the Phase 3 COVE study is an important milestone for the clinical development of mRNA-1273, our vaccine candidate against COVID-19. We are indebted to all of the participants in the study. We would also like to thank the investigators and our partners at clinical trial sites, including our partners from PPD and the NIH, as well as the dedicated Moderna team for their support in completing enrollment," said Stéphane Bancel, Chief Executive Officer of Moderna. "Moderna is committed to rigorous scientific research and the highest data quality standards. We will continue to work in collaboration with regulators to advance mRNA-1273, which we hope will help defeat the COVID-19 pandemic."

The randomized, 1:1 placebo-controlled Phase 3 trial is studying mRNA-1273 at the 100 µg dose level in 30,000 participants in the U.S. 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 target vaccine efficacy (VE) against symptomatic COVID-19 disease which was used for powering assumptions is 60% (95% confidence interval to exclude a lower bound >30%). Data will be reviewed by an independent Data Safety Monitoring Board (DSMB) chartered by NIH. Formal study efficacy analysis will be triggered at 151 cases, with two earlier, interim analyses after 53 and 106 cases. The [ClinicalTrials.gov](#) identifier is NCT04470427.

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. W9111QY-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, the parameters and timing of the Phase 3 study of mRNA-1273, and the process for reviewing data from the Phase 3 study and potential approval of the vaccine by regulators. 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 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 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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