



Moderna Advances Late-Stage Development of its Vaccine (mRNA-1273) Against COVID-19

June 11, 2020

Phase 3 study of 30,000 subjects expected to begin in July 2020 at 100 µg dose level

Manufacturing scale up with Lonza on track to supply 500 million to 1 billion 100 µg doses per year

Completed enrollment of younger adults in the Phase 2 study of mRNA-1273 (n=300); also completed enrollment of the sentinel group of older adults (n=50)

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 11, 2020-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced progress on late-stage development of mRNA-1273, the Company's mRNA vaccine candidate against COVID-19.

Moderna has finalized the Phase 3 study protocol based on feedback from the U.S. Food and Drug Administration (FDA). The randomized, 1:1 placebo-controlled trial is expected to include approximately 30,000 participants enrolled in the U.S. and is expected to be conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The trial's primary endpoint will be the prevention of symptomatic COVID-19 disease; key secondary endpoints include prevention of severe COVID-19 disease (as defined by the need for hospitalization) and prevention of infection by SARS-CoV-2, the virus that causes COVID-19. The primary efficacy analysis will be an event-driven analysis based on the number of participants with symptomatic COVID-19 disease. Based on the results of the Phase 1 study, the 100 µg dose level was chosen as the optimal dose level to maximize the immune response while minimizing adverse reactions. Moderna has completed manufacture of vaccine required to start the Phase 3 study. The Company expects dosing in the Phase 3 study to begin in July.

With the Phase 3 dose being finalized at 100 µg, the Company remains on track to be able to deliver approximately 500 million doses per year, and possibly up to 1 billion doses per year, beginning in 2021 from the Company's internal U.S. manufacturing site and strategic collaboration with Lonza.

"We look forward to beginning our Phase 3 study of mRNA-1273 with some 30,000 participants in July," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "Moderna is committed to advancing the clinical development of mRNA-1273 as safely and quickly as possible to demonstrate our vaccine's ability to significantly reduce the risk of COVID-19 disease."

The first cohort of healthy adults ages 18-54 years (n=300) in the Phase 2 study of mRNA-1273 is fully enrolled, 13 days after the first participant was dosed. The sentinel participants in the cohort of older adults ages 55 years and above (n=50) is fully enrolled. This Phase 2 study, being conducted by Moderna, is evaluating the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. The Company intends to enroll 600 healthy participants across two cohorts of adults ages 18-54 years (n=300) and older adults ages 55 years and above (n=300). Each participant will be assigned to receive placebo, a 50 µg or a 100 µg dose at both vaccinations. Participants will be followed through 12 months after the second vaccination.

On May 6, the U.S. Food and Drug Administration (FDA) [completed](#) its review of the Company's Investigational New Drug (IND) application for mRNA-1273 and on May 11, the FDA granted it [Fast Track](#) designation. On May 18, Moderna [announced](#) initial data from the Phase 1 study of mRNA-1273 led by NIAID. The Phase 1 study is ongoing with the original cohorts in long-term follow-up and enrollment in 9 of 12 cohorts complete. The NIH will be submitting the Phase 1 data to a peer-reviewed clinical publication.

Funding from the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), partially supported the planning for the Phase 2 and Phase 3 studies of mRNA-1273 and is supporting the execution of these studies, as well as the manufacturing process scale-up of mRNA-1273. Moderna will also fund costs required to complete the development of mRNA-1273 including portions of the Phase 3 study and the scale up of manufacturing capacity at the final established dosage in order to obtain licensure for mRNA-1273. A summary of the company's work to date on COVID-19 can be found [here](#).

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 selected by Moderna in collaboration with investigators from Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH. 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 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.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,600 participants have been enrolled in Moderna's infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. Clinical data demonstrate that Moderna's proprietary vaccine technology has been generally well-tolerated and can elicit durable immune responses to viral antigens. Based on clinical experience across Phase 1 studies, the company designated prophylactic vaccines a core modality and is working to accelerate the development of its vaccine pipeline.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to combine multiple mRNAs into a single vaccine, rapid discovery to respond to emerging pandemic threats and manufacturing agility derived from the platform nature of mRNA vaccine design and production. Moderna has built a fully integrated manufacturing plant which enables the promise of the technology platform.

Moderna currently has [nine development candidates](#) in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- Respiratory syncytial virus (RSV) vaccine for older adults (mRNA-1777 and mRNA-1172 or V172 with Merck)
- RSV vaccine for young children (mRNA-1345)
- Human metapneumovirus (hMPV) and parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653)
- COVID-19 vaccine (mRNA-1273)
- Influenza H7N9 (mRNA-1851)

Vaccines against infections transmitted from mother to baby

- Cytomegalovirus (CMV) vaccine (mRNA-1647)
- Zika vaccine (mRNA-1893 with BARDA)

Vaccines against highly prevalent viral infections

- Epstein-Barr virus (EBV) vaccine (mRNA-1189)

To date, Moderna has demonstrated positive Phase 1 data readouts for seven prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV and Zika). Moderna's CMV vaccine is currently in a Phase 2 dose-confirmation study. Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was granted FDA Fast Track designation in August 2019.

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 five years. To learn more, visit 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 potential vaccine against the novel coronavirus, the parameters and timing of the Phase 2 and planned Phase 3 studies of mRNA-1273, the Company's potential manufacturing capabilities and projected vaccine dose production, the submission of Phase 1 data for publication, and costs related to the mRNA-1273 program to be funded by the Company. 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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