Moderna Completes Enrollment of Phase 2 Study of its mRNA Vaccine Against COVID-19 (mRNA-1273)

July 8, 2020

Cohorts of younger adults (n=300) and older adults (n=300) in Phase 2 study fully enrolled

Cohorts of older adults (ages 56-70, n=30) and elderly adults (ages 71 and above, n=30) in NIH-led Phase 1 study completed enrollment; results expected to be published once available

Pivotal Phase 3 study expected to begin in July; manufacture of vaccine required to start Phase 3 study completed

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 8, 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 that it has completed enrollment for both cohorts of the Phase 2 study of its vaccine candidate (mRNA-1273) against COVID-19. mRNA-1273 is Moderna’s second mRNA vaccine for an infectious disease to complete enrollment of a Phase 2 study, following the Company’s CMV Phase 2 study, which was fully enrolled on March 3, 2020.

On June 11, 13 days after the first participant was dosed, the Company announced that the cohort of healthy younger adults ages 18-55 (n=300) and the sentinel group of older adults ages 55 years and above (n=50) in the Phase 2 study of mRNA-1273 was complete. After reviewing the safety data from the sentinel cohort of older adults, on June 25, the Data and Safety Monitoring Committee of the study recommended Moderna to proceed with enrollment for the remainder of the Phase 2 study. The cohort of older adults (n=300) has now been fully enrolled. This Phase 2 placebo-controlled, dose-confirmation study is evaluating the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Each participant is receiving placebo, a 50 μg or a 100 μg dose at both vaccinations.

The Company also announced that the cohorts of older adults (ages 56-70, n=30) and elderly adults (ages 71 and above, n=30) in NIH-led Phase 1 study have completed enrollment. Results are expected to be published once available.

“I would like to thank the healthy volunteer participants, our partners at clinical trial sites and the dedicated Moderna team for their support in completing enrollment of the Phase 2 study of mRNA-1273, our vaccine candidate against COVID-19,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “We are committed to helping address this ongoing public health emergency and continue to focus on our Phase 3 study, which remains on track to start in July, less than seven months from the sequencing of the virus.”

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 at the 100 μg dose level in the U.S. and is expected to be conducted in collaboration with NIAID, subject to regulatory approval. Moderna has completed manufacture of vaccine required to start the Phase 3 study. With the Phase 3 dose 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. In addition, Moderna recently announced a collaboration with Catalent for large-scale, commercial fill-finish manufacturing of mRNA-1273 at Catalent’s biologics facility in Indiana.

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 the VRC. 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. On May 12, the FDA granted mRNA-1273 Fast Track designation.

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 and cardiovascular 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 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). Moderna has been ranked in the top ten of Science’s list of top biopharma industry employers 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, and the Company’s potential manufacturing capabilities and projected vaccine dose production. 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.