



Moderna Announces IND Submitted to U.S. FDA for Phase 2 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

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600 participant Phase 2 study to begin upon IND acceptance and safety data from ongoing NIH-led Phase 1 study

Planning underway for Phase 3 study; study expected to begin in the fall of 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 27, 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 submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the company's mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2) to evaluate mRNA-1273 in Phase 2 and late-stage studies if supported by safety data from the Phase 1 study led by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

Moderna has received initial feedback from the FDA on the design of the planned Phase 2 study, which is expected to begin in the second quarter of 2020. This study will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Each subject will be assigned to receive placebo, a 50 µg or a 250 µg dose at both vaccinations. The company intends to enroll 600 healthy participants across two cohorts of adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300). Participants will be followed through 12 months after the second vaccination.

"Submitting this IND is an important next step in the clinical development of our mRNA vaccine against SARS-CoV-2, and we are moving rapidly to potentially address this global health emergency," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "We look forward to launching this Phase 2 study as soon as possible, which will provide important information about the safety, reactogenicity and immunogenicity of mRNA-1273."

Subject to data from the Phase 1 and Phase 2 studies and discussions with regulators, a Phase 3 study could begin in the fall of 2020. [Funding](#) from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, supported the planning for these studies and also will support the late-stage clinical development programs, as well as the scale-up of mRNA-1273 manufacturing.

"Safe, effective vaccines are critical to ending this pandemic and preventing future outbreaks of SARS-COV-2," said BARDA Acting Director Gary Disbrow, Ph.D. "The next steps announced today for this particular vaccine highlight the value of collaboration among government agencies including BARDA and NIAID, and the private sector, to move vaccines and other medical countermeasures forward as rapidly as possible."

About the NIAID-led Phase 1 Study

An open-label Phase 1 study of mRNA-1273 is being conducted by the National Institute of Allergy and Infectious Diseases under its own Investigational New Drug (IND) application. The Phase 1 study, which began on March 16, 2020, completed enrollment of 45 healthy adult volunteers ages 18 to 55 years in the original three dose cohorts (25 µg, 100 µg and 250 µg). The study is [enrolling](#) an additional six cohorts: three cohorts of older adults (ages 56-70) and three cohorts of elderly adults (ages 71 and above). Data from the original cohort of healthy adult volunteers ages 18 to 55 years will be reported once available.

About mRNA-1273

mRNA-1273 is an mRNA vaccine against SARS-CoV-2 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. A summary of the company's work to date on SARS-CoV-2 can be found [here](#).

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,400 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)

- Novel coronavirus (SARS-CoV-2) 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 Statement

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 planned Phase 2 study of mRNA-1273, the potential timing of a Phase 3 study of mRNA-1273, BARDA funding for clinical studies and manufacturing activities and timing of data from the Phase 1 study 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: 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 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 Annual Report on Form 10-K 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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