



## Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

March 16, 2020

*63 days from sequence selection to Phase 1 study dosing*

*mRNA-1273 is Moderna's 10<sup>th</sup> infectious disease vaccine to begin a clinical trial*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- 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 the first participant has been dosed in the Phase 1 study of the Company's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2). This Phase 1 study is being conducted by the National Institutes of Health (NIH) under its own Investigational New Drug (IND) application.

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 the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of NIH. Manufacture of the first clinical batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

The Phase 1 study is evaluating the safety and immunogenicity of three dose levels of mRNA-1273 (25, 100, 250 µg) administered on a two-dose vaccination schedule, given 28 days apart. A total of 45 healthy adults will be enrolled in the study. Participants will be followed through 12 months after the second vaccination. The primary objective is to evaluate the safety and reactogenicity of a two-dose vaccination schedule of mRNA-1273. The secondary objective is to evaluate the immunogenicity to the SARS-CoV-2 S protein.

"This study is the first step in the clinical development of an mRNA vaccine against SARS-CoV-2, and we expect it to provide important information about safety and immunogenicity. We are actively preparing for a potential Phase 2 study under our own IND," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "We are grateful to NIH for their ongoing collaboration and to CEPI for funding the initial manufacturing of mRNA-1273 and are proud to be included with the many companies, worldwide health agencies and NGOs working on a possible response to the novel coronavirus outbreak."

On January 11, 2020, the Chinese authorities shared the genetic sequence of the novel coronavirus. On January 13, 2020 the VRC and Moderna's infectious disease research team finalized the sequence for the SARS-CoV-2 vaccine and Moderna mobilized toward clinical manufacture. The first clinical batch was completed on February 7, 2020 and underwent analytical testing; it was shipped on February 24, 2020 from Moderna and delivered to NIH from the Company's manufacturing facility in 42 days from sequence selection.

### Next Steps for mRNA-1273

The Company is actively preparing for a potential Phase 2 study under its own IND to build on data from the ongoing Phase 1 study being conducted by the NIH. In order to continue to progress this potential vaccine during the ongoing global public health emergency, Moderna intends to work with the FDA and other government and non-government organizations to be ready for a Phase 2 and any subsequent trials, which are anticipated to include a larger number of subjects and which will seek to generate additional safety and immunogenicity data. Manufacture of the mRNA-1273 material for the potential Phase 2 trial, which could begin in a few months, is underway. Moderna continues to prepare for rapid acceleration of its manufacturing capabilities that could allow for the future manufacture of millions of doses should mRNA-1273 prove to be safe and effective.

### About Coronavirus

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses can be transmitted between animals and people and evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus (SARS-CoV-2) was identified as the cause of pneumonia cases in Wuhan, Hubei Province of China, and additional cases have been found in a growing number of countries.<sup>1,2</sup>

### About Moderna's Prophylactic Vaccines Core 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. Based on clinical experience across six Phase 1 studies, the Company has designated prophylactic vaccines a core modality and intends to accelerate development of its infectious disease vaccine candidates.

The potential advantages of an mRNA approach to prophylactic vaccines include the ability to mimic natural infection to stimulate a more potent immune response, combining 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 in Norwood, MA 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 and parainfluenza virus type 3 (hMPV/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 the Biomedical Advanced Research and Development Authority (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 six prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3 and CMV). 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.

**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, Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, 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) and the Coalition for Epidemic Preparedness Innovations (CEPI). 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](http://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 conduct and timing of the Phase I trial of mRNA-1273, the planning, conduct and timing of a potential Phase 2 and any subsequent trials of mRNA-1273, and potential manufacturing capabilities. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "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; 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](http://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.

<sup>1</sup> "Coronavirus." *World Health Organization*, <https://www.who.int/health-topics/coronavirus>.

<sup>2</sup> "2019 Novel Coronavirus, Wuhan, China." *Centers for Disease Control and Prevention*, <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>.

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