



Moderna Announces Publication in The New England Journal of Medicine of Non-Human Primate Preclinical Viral Challenge Study of its mRNA Vaccine Against COVID-19 (mRNA-1273)

July 28, 2020

mRNA-1273 induced robust neutralizing antibodies and dose dependent increases in T cell responses

mRNA-1273 led to protection against SARS-CoV-2 infection in the lungs and nose of non-human primates

No evidence of vaccine-associated enhanced disease (VAERD) observed

Conference call to be held on Wednesday, July 29, 2020 at 8:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 28, 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 a preclinical study evaluating mRNA-1273, its vaccine candidate against COVID-19, was published in [The New England Journal of Medicine](#). The study showed a two-dose vaccination schedule of mRNA-1273 led to a robust immune response and protection against SARS-CoV-2 infection in the upper and lower airways in non-human primates, without evidence of vaccine-associated enhanced respiratory disease (VAERD).

In the study, immunogenicity and protective efficacy were assessed after a two-dose vaccination schedule of 10 or 100 µg doses of mRNA-1273 or control given four weeks apart (n=24; 8 per group). Four weeks after the second vaccination, animals were challenged with high doses of SARS-CoV-2 through intranasal and intratracheal routes.

After two vaccinations, the immune response observed in this non-human primate study was consistent with the [recently reported](#) Phase 1 human study of mRNA-1273, also published in [The New England Journal of Medicine](#). At the 10 µg dose, the geometric mean titer (GMT, ID50) measured in a pseudovirus (PsV) neutralization assay was 103, similar to the GMT for a panel of convalescent sera reported previously (109), and below the GMT achieved by mRNA-1273 in the Phase 1 human study at the 100 µg dose (231) in the same PsV assay. At the higher dose in the non-human primates (100 µg) neutralizing antibody titers increased further, with PsV GMT reaching 1,862. Vaccination also led to a significant increase in T cell responses, primarily Th1 CD4 T cells.

Two doses of mRNA-1273 provided protection against lung inflammation following viral challenge with SARS-CoV-2 in non-human primates at both the 10 µg and 100 µg dose levels. In addition, both the 10 µg and 100 µg dose groups demonstrated protection against viral replication in the lungs, with the 100 µg dose also protecting against viral replication in the nose of the animals. Of note, none of the eight animals in the 100 µg group showed detectable viral replication in the nose compared to six out of eight in the placebo group on day 2.

"This important preclinical study shows that mRNA-1273 protected against a high dose SARS-CoV-2 infection in non-human primates and prevented pulmonary disease in all animals, further supporting the clinical advancement of mRNA-1273," said Stephen Hoge, M.D., President at Moderna. "We believe this is the first demonstration of control of viral replication within two days of challenge in both the nose and lungs in non-human primates by a vaccine against COVID-19. Given the similarity between the protective immune response generated by mRNA-1273 in this study and the immune response seen in humans in the recently published Phase 1 clinical data for the vaccine, we remain cautiously optimistic that mRNA-1273 will be able to prevent COVID-19 disease and may also slow the spread of SARS-CoV-2 by shortening the duration of shedding."

The Biomedical Advanced Research and Development Authority (BARDA), part 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 research and development of mRNA-1273 with federal funding under Contract no. 75A50120C00034. A summary of the company's work to date on COVID-19 can be found [here](#).

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:00 a.m. ET on Wednesday, July 29, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 6278397. A webcast of the call will also be available under "Events and Presentations" in the Investors section of the Moderna website at [investors.modernatx.com](#). The archived webcast will be available on Moderna's website approximately two hours after the conference call.

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 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. Moderna recently announced that data from an interim analysis of the Phase 1 study of mRNA-1273 was [published](#) in [The New England Journal of Medicine](#). On July 8, the Company's Phase 2 study of mRNA-1273 [completed enrollment](#). On July 27, the [Phase 3 COVE study](#) of mRNA-1273, being conducted in collaboration with NIH and BARDA, began.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,900 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 eight prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3, CMV, Zika and COVID-19). 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, and the potential for mRNA-1273 to prevent COVID-19 disease and slow the spread of SARS-CoV-2. 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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Source: Moderna, Inc.