Modern mRNA-1273 was generally safe and well tolerated.

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Preclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available. In this study, vaccination with mRNA-1273 prevented viral replication in the lungs of animals challenged with SARS-CoV-2. Neutralizing titers in Phase 1 clinical trial participants at the 25 µg and 100 µg dose levels were consistent with neutralizing titers that were protective in the mouse challenge model.

Based on the interim Phase 1 data, the Moderna-led Phase 2 study will be amended to study two dose levels, 50 µg and 100 µg, with the aim of selecting a dose for pivotal studies. The NIAID-led Phase 1 study is being amended to include a 50 µg dose level cohort across each of the three age groups. Moderna anticipates the dose for the Phase 3 study to be between 25 µg and 100 µg and expects Phase 3 trial initiation in July, subject to finalization of the clinical trial protocol.

“These interim Phase 1 data, while early, demonstrate that vaccination with mRNA-1273 elicits an immune response of the magnitude caused by natural infection starting with a dose as low as 25 µg,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “When combined with the success in preventing viral replication in the lungs of a preclinical challenge model at a dose that elicited similar levels of neutralizing antibodies, these data substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease and advance our ability to select a dose for pivotal trials.”

“With today’s positive interim Phase 1 data and the positive data in the mouse challenge model, the Moderna team continues to focus on moving as fast as safely possible to start our pivotal Phase 3 study in July and, if successful, file a BLA,” said Stéphane Bancel, Chief Executive Officer at Moderna. “We are investing to scale up manufacturing so we can maximize the number of doses we can produce to help protect as many people as we can from SARS-CoV-2.”

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), supported the planning for the Phase 2 and Phase 3 studies of mRNA-1273 and will also support the execution of these studies, as well as the scale-up of mRNA-1273 manufacturing both at the Company’s facilities and that of its strategic collaborator, Lonza Ltd.

Conference Call and Webcast Information

Moderna will host a live conference call and webcast at 8:30 a.m. ET on Monday, May 18, 2020. To access the live conference call, please dial 866-922-5184 (domestic) or 409-937-8950 (international) and refer to conference ID 2186342. A webcast of the call will also be available under...
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.

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 allowing it to proceed to a Phase 2 study, which is expected to begin shortly. On May 12, the FDA granted mRNA-1273 Fast Track designation. Moderna is finalizing the protocol for a Phase 3 study, expected to begin in July 2020. 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 named a top biopharmaceutical employer by Science 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 Phase 1 and planned Phase 2 and 3 studies of mRNA-1273, the Company’s investment in manufacturing, and the Company’s intentions regarding 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 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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