



Moderna Receives Confirmation of Eligibility for Submission of Marketing Authorization Application to the European Medicines Agency for mRNA Vaccine Against COVID-19 (mRNA-1273)

October 14, 2020

Confirmation underscores Moderna's commitment to make its vaccine available in the EU

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 14, 2020-- [Moderna Inc.](#), (Nasdaq:MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that it has received written confirmation from the European Medicines Agency (EMA) that mRNA-1273, the Company's vaccine candidate against COVID-19, is eligible for submission of an application for a European Union Marketing Authorization under the Agency's centralized procedure. Confirmation of eligibility was given in response to the submission of a letter of intent enabling Moderna to evaluate the opportunity for submitting a Marketing Authorization Application (MAA) for mRNA-1273 with the EMA. This submission follows [positive results](#) from a preclinical viral challenge study and the positive interim analysis of the Phase 1 study of mRNA-1273 in healthy [adults](#) (ages 18-55 years) and [older adults](#) (ages 56-70 and 71+) published in the *New England Journal of Medicine*.

Moderna appreciates the EMA's effective response to this serious public health emergency by establishing a Fast-Track framework, which includes rapid scientific advice, rolling review, and accelerated assessment.

"We are pleased with the productive interactions with the European regulatory authorities at the National level and at the EMA level to date and we appreciate their valuable guidance and confidence in Moderna to pursue an MAA submission for approval in Europe for our COVID-19 vaccine candidate, mRNA-1273. European partners, investors and citizens have been part of Moderna from the beginning of the company and have played an important role in Moderna's progress," said Stéphane Bancel, Moderna's Chief Executive Officer. "We are committed to developing a safe and effective vaccine following the guidance of regulatory agencies and we will continue our ongoing dialogue with the EMA. Moderna is scaling up global manufacturing to be able to deliver approximately 500 million doses per year and possibly up to 1 billion doses per year, beginning in 2021."

In Europe, the Company is working with its strategic manufacturing partners, Lonza of Switzerland and ROVI of Spain, for manufacturing and fill-finish outside of the United States. This is a dedicated supply chain to support Europe and countries other than the United States that enter into purchase agreements with Moderna.

The Phase 1 interim analysis showed that mRNA-1273 was generally well-tolerated across all age groups and induced rapid and strong immune responses against SARS-CoV-2. In the [18-55 age group](#), neutralizing antibody titers were observed in 100% of evaluated participants and at the 100 µg dose level selected for Phase 3, the geometric mean titers were above those seen in convalescent sera. Similarly, mRNA-1273 induced consistently high levels of pseudovirus neutralization antibody titers in all participants in the [56-70 and 71+ age groups](#). In addition, vaccination with mRNA-1273 elicited Th1-biased CD4 T cell responses in all age groups.

mRNA-1273 is currently being studied in a Phase 3 randomized, 1:1 placebo-controlled trial of 30,000 participants at the 100 µg dose level in the U.S. As of Friday, October 9, the Phase 3 COVE study has enrolled approximately 28,618 participants with more than 22,194 having received their second vaccination. The [clinicaltrials.gov](#) identifier is NCT04470427. For more information about the Phase 3 COVE study, [click here](#).

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. Across Moderna's pipeline, more than 30,000 healthy volunteers and patients have been enrolled in Moderna's clinical studies, including the Phase 3 study of mRNA-1273. 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 [seven development candidates](#) in its prophylactic vaccines modality, including:

Vaccines against respiratory infections

- 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 vaccine (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 named a top biopharmaceutical employer by *Science* 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 statements regarding: the Company's plans to submit a single marketing application to the EMA for mRNA-1273; the potential for mRNA-1273 to be marketed in EU member states and other countries; the potential for mRNA-1273 to induce rapid and strong immune responses against SARS-CoV-2 in individuals of different ages; plans for the manufacture of mRNA-1273 and the scale of anticipated production; and the potential advantages of mRNA-based prophylactic vaccines and the ability to combine multiple mRNAs into a single vaccine. 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: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA, EMA or other regulatory agencies, the FDA, EMA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those 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.