



Moderna Confirms Advanced Discussions with European Commission to Supply Europe with 80 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273)

August 24, 2020

European Commission would have the option to purchase an additional 80 million doses for a total of up to 160 million doses

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 24, 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 the Company has concluded advanced exploratory talks with the European Commission to supply 80 million doses of mRNA-1273, Moderna's vaccine candidate against COVID-19, as part of the European Commission's goal to secure early access to safe and effective COVID-19 vaccines for Europe.

The potential purchase agreement with the European Commission of 80 million doses provides for an option for Member States to purchase an additional 80 million doses for a total of up to 160 million doses. The discussions are intended to ensure that Member States have access to Moderna's vaccine. The Phase 3 study of mRNA-1273 began on July 27 and enrollment of approximately 30,000 participants is on track to complete in September. 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.

"We appreciate the European Commission's collaboration in helping to ensure that Europeans will have access to a safe and effective vaccine, and we are proud that the European Commission has recognized the potential of our mRNA vaccine technology. 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, CEO of Moderna. "We are scaling up our international manufacturing capacity outside of the United States with our strategic partners, Lonza in Switzerland and Rovi in Spain, to be in a position to address this global health emergency with a vaccine that is widely available once approved for use."

Over the past nine years, Moderna has invested in creating and developing a novel platform for designing and manufacturing a new class of mRNA-based vaccines. The investments in this proprietary platform have enabled Moderna to expeditiously create, manufacture and clinically develop mRNA-1273 to potentially address the current COVID-19 pandemic. A summary of the company's work to date on COVID-19 can be found [here](#).

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 the National Institute of Allergy and Infectious Disease's (NIAID) 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 the National Institutes of Health (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. On May 29, the first participants in each age cohort: healthy adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300) were dosed in the Phase 2 study of mRNA-1273. On July 8, the [Phase 2 study](#) completed enrolment.

The Phase 3 COVE study of mRNA-1273, being conducted in collaboration with the NIH and the Biomedical Advanced Research and Development Authority (BARDA), began on July 27; enrollment is on track to complete in September. Results from a non-human primate preclinical viral challenge study evaluating mRNA-1273 were recently [published](#) in *The New England Journal of Medicine*. On July 14, an interim analysis of the original cohorts in the NIH-led Phase 1 study of mRNA-1273 was [published](#) in *The New England Journal of Medicine*.

About Moderna's Prophylactic Vaccines Modality

Moderna scientists designed the company's prophylactic vaccines modality to prevent infectious diseases. More than 1,900 participants, prior to enrolling the Phase 3 study of mRNA-1273, 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 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. Moderna's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing the Company 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, cardiovascular diseases, and autoimmune and inflammatory 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; 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 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, but not limited to, statements concerning terms of the Company's potential supply agreement with the European Commission, the timing of enrollment in the Phase 3 study of mRNA-1273 and the Company's ability to produce doses of mRNA-1273 on envisaged timelines. 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 Company's ability to reach a final agreement with the European Commission on the supply of mRNA-1273; the ability to manufacture and deliver doses at the scale required by any potential agreement with the European Commission and other customers; the lack of a guarantee Member States of the European Commission will agree to and exercise their option to purchase additional doses; 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 U.S. Food and Drug Administration (FDA), European Medicines Agency (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; 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 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200824005381/en/): <https://www.businesswire.com/news/home/20200824005381/en/>

Media:

Florence Hugenholtz (FTI Consulting)
+32 470.26.91.30
Florence.Hugenholtz@fticonsulting.com

Harriet Barham (FTI Consulting)
+32 474 819 629
Harriet.barham@fticonsulting.com

Colleen Hussey
Senior Manager, Corporate Communications
617-335-1374
Colleen.Hussey@modernatx.com

Investors:

Lavina Talukdar

Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.