



Moderna Announces the European Commission's Approval of Advance Purchase Agreement for Initial 80 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273)

November 25, 2020

Option granted to European Commission to purchase up to an additional 80 million doses

Agreement reflects Moderna's commitment to make its vaccine available in multiple countries

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 25, 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 European Commission has approved an agreement to secure 80 million doses of mRNA-1273, Moderna's vaccine candidate against COVID-19, as part of the European Commission's goal to secure access to a safe and effective COVID-19 vaccine for Europe.

Under the terms of the proposed agreement, the European Commission has the option to increase their purchase of mRNA-1273, from 80 million doses to a total of up to 160 million doses. The agreement will be finalized following a brief review period by the European Union Member States. This announcement follows the conclusion of advanced exploratory talks with the European Commission that began on August 24, 2020. Delivery of the vaccine could begin as early as the first quarter 2021 if it is approved for use by the European Medicines Agency (EMA) human medicines committee (CHMP), which started a rolling review of mRNA-1273 on November 17.

"We appreciate the confidence the European Commission has demonstrated in our mRNA vaccine platform by including mRNA-1273 in their portfolio of vaccines. We recognize that tackling this global pandemic will require a number of solutions, and we are proud of the role Moderna has been able to play in this global effort," said Stéphane Bancel, Chief Executive Officer of Moderna. "We have scaled up our manufacturing capacity outside of the United States with our strategic partners, Lonza and Rovi, to be able to deliver approximately 500 million doses per year and possibly up to 1 billion doses per year beginning in 2021, if approved."

In Europe, Moderna 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 Company remains on track to manufacture 500 million to 1 billion doses globally in 2021. If the relevant regulatory approvals are granted, Moderna expects to begin shipping mRNA-1273 to the European Union beginning in December 2020.

On November 16, Moderna announced that the independent, U.S. NIH-appointed Data Safety Monitoring Board (DSMB) for the Phase 3 study of mRNA-1273 has informed Moderna that the trial has met the statistical criteria pre-specified in the study protocol for efficacy, with a vaccine efficacy of 94.5%. This study, known as the COVE study, enrolled more than 30,000 participants in the U.S. and is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

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 six 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 terms of the Company's anticipated sale of mRNA-1273 to the European Commission and European Union Member States; the anticipated finalization of the agreement for such sale; the timing for the delivery of mRNA-1273 to the European Commission; 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; mRNA-1273's efficacy and its ability to prevent infection or mitigate symptoms of COVID-19; and plans for the manufacture of mRNA-1273 and the scale of anticipated 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: 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20201125005570/en/): <https://www.businesswire.com/news/home/20201125005570/en/>

Moderna

Media:

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

Investors:

Lavina Talukdar
Senior Vice President & Head of Investor Relations
617-209-5834
Lavina.Talukdar@modernatx.com

Source: Moderna, Inc.