



## European Commission Exercises Option for Additional 80 Million Doses of Moderna's COVID-19 Vaccine Candidate

December 18, 2020

*Total of 160 million doses ordered by the European Commission to date*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 18, 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 exercised its option to purchase an additional 80 million doses of mRNA-1273, Moderna's COVID-19 vaccine candidate, bringing its confirmed order commitment to 160 million doses.

The first deliveries of mRNA-1273 to European countries from Moderna's dedicated European supply chain are expected to commence early in 2021 following regulatory approval by the EMA. These deliveries are subject to receipt of the positive opinion from the European Medicines Agency's (EMA) scientific committee for human medicines (CHMP) and the European Commission's Decision regarding the Conditional Marketing Authorisation (CMA) for the vaccine. The CHMP meeting is planned for January 6, 2021.

"We appreciate the confidence in Moderna and mRNA-1273, our COVID-19 vaccine candidate, demonstrated by today's increased supply agreement with the European Commission" said Stéphane Bancel, Chief Executive Officer of Moderna. "As we shift our focus now to prepare for the delivery of our vaccine candidate, pending a positive opinion from the EMA and other regulators, we remain committed to working with governments and partners globally to address this pandemic."

### Moderna's COVID-19 Vaccine Supply Agreements

Moderna has confirmed the following supply agreements of committed orders totalling more than 470 million doses:

- United States: 200 million doses with option for an additional 300 million doses
- European Union: 160 million doses
- Japan: 50 million doses
- Canada: 40 million doses with option for an additional 16 million doses
- Switzerland: 7.5 million doses
- United Kingdom: 7 million doses
- Israel: 6 million doses
- Qatar
- Singapore
- Other countries, which have placed orders and have not been disclosed.

Moderna is working with the CHMP, EMA and European Commission as well as global stakeholders to be prepared for distribution of mRNA-1273, in the event that it receives Conditional Marketing Authorisation and similar global authorizations and approvals.

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 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 the 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: 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 enrollment.

Results from the second interim analysis of the NIH-led Phase 1 study of mRNA-1273 in the 56-70 and 71+ age groups were published on September 29 in *The New England Journal of Medicine*. On July 28, results from a non-human primate preclinical viral challenge study evaluating mRNA-1273 were 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*. On November 30, Moderna announced the primary efficacy analysis of the Phase 3 study of mRNA-1273 conducted on 196 cases. On November 30, the Company also announced that it filed for Emergency Use Authorization with the U.S. FDA and a Conditional Marketing Authorisation (CMA) with the European Medicines Agency. On December 3, a letter to the editor was published in *The New England Journal of Medicine* reporting that participants in the Phase 1 study of mRNA-1273, its COVID-19 vaccine candidate, retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination). mRNA-1273 currently is not approved for use by any regulatory body.

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) is supporting the continued research and development of mRNA-1273 with \$955 million in federal funding under contract no. 75A50120C00034. BARDA is reimbursing Moderna for 100 percent of the allowable costs incurred by the Company for conducting the program described in the BARDA contract. The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

## 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, 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, and BARDA. Moderna has been named a top biopharmaceutical employer by Science for the past six years. To learn more, visit [www.modernatx.com](http://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 terms of the Company's sale of mRNA-1273 to the European Commission; the timing for the delivery of mRNA-1273 to the European Commission; plans to request regulatory approval for the distribution of mRNA-1273 in the Member States of the European Union; 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: 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 safety, tolerability and efficacy profile of mRNA-1273 observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; 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; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for mRNA-1273; whether and when any biologics license applications and/or emergency use authorization applications may be filed and ultimately approved by regulatory authorities; 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](http://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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