



Moderna Announces Amendment to Current Supply Agreement with United Kingdom Government for an Additional 2 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273)

November 29, 2020

UK government has now secured 7 million doses of mRNA-1273

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 29, 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 a supply agreement with the UK government for an additional 2 million doses of mRNA-1273, Moderna's vaccine candidate against COVID-19, to the United Kingdom beginning in March 2021. The UK government has now secured 7 million doses of mRNA-1273. This confirmation comes as the UK continues its efforts to secure access to safe and effective COVID-19 vaccines by establishing a broad portfolio of the most promising vaccines.

"We appreciate the collaboration with the UK government as with many other governments and other key partners around the world," said Stéphane Bancel, Chief Executive Officer of Moderna. "For almost a decade, Moderna has invested in creating and developing a novel platform for designing and manufacturing a new class of mRNA-based vaccines. We are proud of the progress on mRNA-1273 we have made to date including the positive interim analysis from our Phase 3 COVE study."

On November 16, [Moderna announced](#) that the independent, NIH-appointed Data Safety Monitoring Board (DSMB) for the Phase 3 study of mRNA-1273, its vaccine candidate against COVID-19, 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.

On October 27, 2020, Moderna received confirmation that the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) in the United Kingdom started the rolling review process of mRNA-1273.

Moderna continues to scale up its 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. 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. To learn more about Moderna's work on mRNA-1273, visit www.modernatx.com/COVID19.

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*. mRNA-1273 currently is not approved for use by any regulatory body.

BARDA 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 provide up to \$1.525 billion to purchase supply of mRNA-1273 under U.S. Department of Defense Contract No. W911QY-20-C-0100.

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 Company's development of a potential vaccine (mRNA-1273) against the novel coronavirus, mRNA-1273's efficacy and its ability to prevent infection or mitigate symptoms of COVID-19, the terms of the Company's anticipated sale of mRNA-1273 to the government of the United Kingdom; the timing for the delivery of mRNA-1273 to the United Kingdom; plans to submit an application for regulatory approval for the distribution of mRNA-1273 to the MHRA; 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 fact that the safety and efficacy of mRNA-1273 has not yet been established; despite having ongoing interactions with the FDA, MHRA or other

regulatory agencies, the FDA, MHRA 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; 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. 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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