Canada Exercises Increased Option for Total of 40 Million Doses of mRNA Vaccine Candidate Against COVID-19 (mRNA-1273)

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 7, 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 Canadian Government has increased its confirmed order commitment by 20 million doses of Moderna's vaccine candidate against COVID-19, mRNA-1273, bringing its confirmed order commitment to 40 million doses.

"This increased supply agreement from the Canadian government today reaffirms the confidence in our COVID-19 vaccine candidate and we appreciate our collaboration with the Canadian government as with many other governments and other key partners around the world," said Stephane Bancel, Moderna's Chief Executive Officer. "For ten years, Moderna has invested in creating and developing a novel platform for designing and manufacturing a new class of mRNA-based vaccines. The recent positive efficacy analysis from our Phase 3 COVE study is an encouraging step in the development of mRNA-1273."

Moderna remains on track to be able to start delivery of its COVID-19 vaccine candidate to help protect Canadians following regulatory approval by Canadian health authorities. Moderna could ship its COVID-19 vaccine as soon as December if regulatory approval is granted this month. The Company has already initiated the rolling review process with Health Canada and intends to seek Prequalification (PQ) and/or Emergency Use Listing (EUL) with the World Health Organization (WHO). The Canadian vaccine supply will be sourced from Moderna's European production capacity with its strategic manufacturing partner Lonza in Switzerland, and ROVI in Spain for fill-finish services.

On November 30, Moderna announced that the primary efficacy analysis of the Phase 3 study of mRNA-1273 conducted on 196 cases confirmed the high efficacy observed at the first interim analysis. The data analysis indicates a vaccine efficacy of 94.1%. Safety data continue to accrue and the study continues to be monitored by an independent, NIH-appointed Data Safety Monitoring Board (DSMB). Based on prior analysis, the most common solicited adverse reactions included injection site pain, fatigue, myalgia, arthralgia, headache, and erythema/redness at the injection site. Solicited adverse reactions increased in frequency and severity in the mRNA-1273 group after the second dose. The Phase 3 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, 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 with 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 BARDA. 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 regarding the Company's development of a potential vaccine against the novel coronavirus, the potential for mRNA-1273 to prevent COVID-19 disease and slow the spread of SARS-CoV-2, the safety profile for mRNA-1273, plans for the supply of mRNA-1273 to the Canadian government, including the anticipated timing for the delivery of mRNA-1273, the Company's plans to seek regulatory approval from Health Canada and the World Health Organization for the use and distribution of mRNA-1273, and plans for the manufacturing and distribution of mRNA-1273. 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 or other regulatory agencies, the FDA 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. 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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