Moderna Receives FDA Advisory Committee Vote Supporting Emergency Use for Moderna's Vaccine Against COVID-19 in the United States

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 17, 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 confirmed that the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended that the FDA grant an Emergency Use Authorization (EUA) for the Company's COVID-19 vaccine candidate, mRNA-1273. 20 VRBPAC members recommended for EUA, 0 members voted against, and 1 abstained.

"We were grateful for the opportunity to present the clinical data package for our mRNA vaccine against COVID-19 to the FDA's advisory committee today. We thank the committee for their review and for their positive recommendation in support of Emergency Use Authorization," said Stéphane Bancel, Chief Executive Officer of Moderna. "We have been working with the U.S. Centers for Disease Control and Prevention and Operation Warp Speed to prepare for the distribution of mRNA-1273, if the FDA chooses to grant an Emergency Use Authorization. We look forward to getting our vaccine to people in the U.S. to help address this ongoing public health emergency."

The VRBPAC based its recommendation on the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study announced on November 30. The primary efficacy analysis conducted on 196 cases indicated a vaccine efficacy rate of 94.1%. The most common solicited adverse reactions (ARs) after the two-dose series included injection site pain (88.2%), erythema (8.6%), swelling (12.2%), and ipsilateral lymphadenopathy (14.2%). While the majority of these ARs were grade 1 (mild) or grade 2 (moderate), there was a higher occurrence of grade 3 (severe) reactions in the mRNA-1273 group and after the second injection. The majority of local solicited ARs occurred within the first one to two days after injection and generally persisted for a median of one to two days. Safety data continue to accrue, and the study continues to be monitored by an independent Data Safety Monitoring Board (DSMB) appointed by the National Institutes of Health (NIH). All participants in the COVE study will be monitored for two years after their second dose to assess long-term protection and safety.

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 (NIAID) 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.

FDA advisory committees provide non-binding recommendations. The FDA will take the VRBPAC's recommendation into consideration in making a final decision on approval or authorization. Under an EUA, the FDA has the authority to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions during a declared public health emergency when there are no adequate, approved, and available alternatives.

Shipping and Temperature Update

Also presented at today's VRBPAC meeting, Moderna has expanded the handling guidance for mRNA-1273 to include local transport under controlled conditions in a liquid state at 2-8°C (36° to 46°F). In some cases, this may be the only practical means of distribution from clinics and for remote locations. This important update will help facilitate distribution to the final site of administration. Recognizing that shipping and handling of product can be a barrier to vaccination, Moderna remains committed to supporting efficient distribution. Moderna previously announced that mRNA-1273 remains stable at standard refrigerator temperatures of 2° to 8°C (36° to 46°F) for 30 days.

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 BARDA. 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 statements 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, the potential Emergency Use Authorization for mRNA-1273 by the FDA, ongoing safety monitoring under the COVE Study, and the conditions under which mRNA-1273 can be shipped, stored and administered. 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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Moderna
Media:
Colleen Hussey
Director, 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.