U.S. CDC Advisory Committee on Immunization Practices Recommends Vaccination with Moderna's COVID-19 Vaccine for Persons 18 Years and Older

December 20, 2020

Recommendation follows yesterday's U.S. FDA authorization for emergency use of the Moderna COVID-19 Vaccine

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 19, 2020-- Moderna, Inc., (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines today announced that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted today to recommend the use of the Moderna COVID-19 vaccine in people 18 years of age and older under the Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA). The committee is comprised of independent health experts. 11 ACIP members voted in favor of the vaccine and 0 members voted against.

Today's ACIP recommendation follows the December 1, 2020 ACIP recommendation for a Phase 1a rollout in which the first priority for COVID-19 vaccines is given to healthcare personnel treating patients and residents in long-term care facilities. This ACIP recommendation will be forwarded to the Director of the CDC and the U.S. Department of Health and Human Services (HHS) for review and adoption.

"Since we began this journey in January, our goal has always been to protect as many people as possible and this ACIP recommendation is another step forward in our quest to address this devastating pandemic with a vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna. "Healthcare workers have been on the front lines of the fight against the virus and are an inspiration to us all. We look forward to vaccinations of this important population starting this week."

The ACIP advises the CDC on the populations and circumstances for which vaccines should be used. The Committee based its recommendation on clinical evidence supporting the Moderna COVID-19 Vaccine including data from Moderna's 30,000 participant Phase 3 study and ACIP's interim guidance on the allocation of initial vaccine doses. The Moderna COVID-19 Vaccine was authorized for distribution and use under an EUA on December 18, 2020. The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use, unless terminated or revoked. Moderna will continue to gather additional data and plans to file a Biologics License Application (BLA) with the FDA requesting full licensure in 2021.

Under Operation Warp Speed, the U.S. Department of Defense (DoD), in partnership with HHS and the CDC, will manage allocation and distribution of the vaccine in the United States. Approximately 20 million doses will be delivered to the U.S. government by the end of December 2020. The Company expects to have between 100 million and 125 million doses available globally in the first quarter of 2021, with 85-100 million of those available in the U.S.

Please see the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information available at www.modernatx.com/covid19vaccine-eua.

A summary of the company's work to date on COVID-19 can be found here.

About the Moderna COVID-19 Vaccine

The Moderna COVID-19 Vaccine (previously referred to as 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 the vaccine was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. On May 12, the FDA granted the Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine 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 the vaccine 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 the vaccine was published in *The New England Journal of Medicine*. On November 30, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine 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 Authorization (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 the Moderna COVID-19 Vaccine retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination). On December 18, 2020, the FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older.

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 the Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine under U.S. Department of Defense contract no. W911QY-20-C-0100.

The Moderna COVID-19 vaccine has not been approved or licensed by the FDA, or any other health authority, but it has been authorized for emergency use by the FDA under an EUA.

AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.
- The Moderna COVID-19 Vaccine may not protect all vaccine recipients.
- Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.
- Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
- Vaccination providers must complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words " Moderna COVID-19 Vaccine EUA " in the description section of the report.

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 vaccine against the novel coronavirus, the potential for the Moderna COVID-19 Vaccine to prevent COVID-19 disease and slow the spread of SARS-CoV-2, plans for the supply of the Moderna COVID-19 Vaccine to the U.S. Government, plans for the manufacturing and distribution of the Moderna COVID-19 Vaccine, and plans related to seeking approval for a Biologics License Application for the Moderna COVID-19 Vaccine from the FDA. 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 the Moderna COVID-19 Vaccine 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 the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or additional emergency use authorization applications may be filed in various jurisdictions 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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