# Moderna Announces Publication of Results from the Pivotal Phase 3 Trial of the Moderna COVID-19 Vaccine in The New England Journal of Medicine

December 31, 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 31, 2020-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines today announced that interim safety and primary efficacy results from the Phase 3 trial of the Moderna COVID-19 Vaccine (mRNA-1273) were published in the *New England Journal of Medicine*. The 100 µg two-dose regime of the Moderna COVID-19 Vaccine given 28 days apart was well-tolerated and demonstrated vaccine efficacy of 94.1% against COVID-19. 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), 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.

The primary endpoint of the Phase 3 COVE study was based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine. This final analysis was based on 196 cases, of which 185 cases of COVID-19 were observed in the placebo group versus 11 cases observed in the Moderna COVID-19 Vaccine group, corresponding to a 94.1% vaccine efficacy (95% CI 89.3-96.8%; p<0.0001).

A secondary endpoint analyzed severe cases of COVID-19 and included 30 severe cases (as defined in the study protocol) in this analysis. All 30 cases occurred in the placebo group and none in the mRNA-1273 vaccinated group. There was one COVID-19-related death in the study to date, which occurred in the placebo group.

The Moderna COVID-19 Vaccine exhibited a favorable tolerability and safety profile. Based on a data cut-off date of November 25, 2020, the study had a median of 9 weeks of safety data available after the second dose and contributed to the main safety dataset. Baseline demographic characteristics were generally balanced between the placebo and vaccine groups. Among these participants, the mean age was 51.4 years, 47.3% were female, 24.8% were older than 65 years, and 16.7% were under the age of 65 but have high-risk chronic diseases that put them at increased risk of severe COVID-19, such as diabetes, severe obesity and cardiac disease. Participants from communities of color represented 37% of the study population, similar to the diversity of the U.S. at large. This included 20.5% participants who identify as Hispanic or LatinX, and 10.2% participants who identify as Black or African American.

The most common solicited adverse reactions (ARs) after the two-dose series was injection site pain (86.0%). Solicited systemic adverse events occurred more often in the Moderna COVID-19 vaccine group (54.9% and 79.4%) than in the placebo (42.2% and 36.5%) group after both the first dose and the second dose respectively and were most commonly headache, fatigue and myalgia. While the majority of these ARs were mild (grade 1) or moderate (grade 2), there was a higher occurrence of severe (grade 3) reactions in the Moderna COVID-19 Vaccine group after the first (2.9%) and second (15.8%) injections. 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 continues to accrue, and the study continues to be monitored by an independent Data Safety Monitoring Board (DSMB) appointed by the 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 COVE study is ongoing and will continue to follow participants for two years. Additional data to be collected will include longer term safety follow-up, duration of protection against COVID-19, and efficacy against asymptomatic SARS-CoV-2 infection. Moderna is also conducting a Phase 2/3 study of the Moderna COVID-19 vaccine in adolescents 12 to under 18 years of age. Additional studies are planned to evaluate the Moderna COVID-19 Vaccine in pregnant women, children younger than 12 years, and those in special risk groups, such as the immunocompromised.

**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.

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

**AUTHORIZED USE:**

The Moderna COVID-19 Vaccine has been authorized for emergency use by the U.S. Food and Drug Administration (FDA) 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 and has been authorized by Health Canada for the immunization of Canadians 18 years of age and older under an Interim Order. Moderna has submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.

**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 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 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, and the safety profile for the Moderna COVID-19 Vaccine. 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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