Moderna Announces it has Shipped Variant-Specific Vaccine Candidate, mRNA-1273.351, to NIH for Clinical Study

February 24, 2021

Company also provides update on strategy for addressing SARS-CoV-2 variants of concern

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 24, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, announces that it has completed manufacturing of clinical trial material for its variant-specific vaccine candidate, mRNA-1273.351, against the SARS-CoV-2 variant known as B.1.351 first identified in the Republic of South Africa, and has shipped doses to the National Institutes of Health (NIH) for a Phase 1 clinical trial that will be led and funded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID). The Company also is providing an update on its strategy for addressing SARS-CoV-2 variants of concern.

While initial data confirms that the Moderna COVID-19 Vaccine (mRNA-1273) provides neutralizing activity against variants of concern, out of an abundance of caution, Moderna is pursuing two strategies against these variants, subject to U.S. Food and Drug Administration (FDA) review. First, the Company is evaluating booster doses of vaccine to increase neutralizing immunity against the variants of concern. Moderna plans to evaluate three approaches to boosting, including:

- A variant-specific booster candidate, mRNA-1273.351, based on the B.1.351 variant first identified in the Republic of South Africa, at the 50 µg dose level and lower.
- A multivalent booster candidate, mRNA-1273.211, which combines mRNA-1273, Moderna's authorized vaccine against ancestral strains, and mRNA-1273.351 in a single vaccine at the 50 µg dose level and lower.
- A third dose of mRNA-1273, the Moderna COVID-19 Vaccine, as a booster at the 50 µg dose level. The Company has already begun dosing this cohort with the booster.

Second, the Company plans to evaluate mRNA-1273.351 and mRNA-1273.211 as a primary vaccination series for those who are seronegative. These candidates will be evaluated in a two-dose series at the 100 µg dose level and lower.

Consistent with the recently updated FDA Guidance for Industry, the Company plans to evaluate immunogenicity and safety in participants who have not received a COVID-19 vaccine as well as participants in clinical studies who previously received the mRNA-1273 vaccine.

NIAID, part of the National Institutes of Health (NIH), will conduct a Phase 1 clinical trial to determine if mRNA-1273.351 can boost immunity against the variants of concern. Moderna will provide doses of mRNA-1273.351 to the NIH. NIAID will initiate this study after receiving safe-to-proceed authorization from the FDA. NIAID will provide additional information when the trial begins, and details will also be available on clinicaltrials.gov. In parallel, the Company will be conducting its own clinical studies to support regulatory filings for any booster vaccine or updated primary vaccine.

"We look forward to beginning the clinical study of our variant booster and are grateful for the NIH's continued collaboration to combat this pandemic," said Stéphane Bancel, Chief Executive Officer of Moderna. "As we seek to defeat COVID-19, we must be vigilant and proactive as new variants of SARS-CoV-2 emerge. Leveraging the flexibility of our mRNA platform, we are moving quickly to test updates to the vaccines that address emerging variants of the virus in the clinic. Moderna is committed to making as many updates to our vaccine as necessary until the pandemic is under control. We hope to demonstrate that booster doses, if necessary, can be done at lower dose levels, which will allow us to provide many more doses to the global community in late 2021 and 2022 if necessary."

These studies will inform the Company's regulatory strategy with the U.S. FDA and regulatory agencies outside of the U.S. The current Moderna COVID-19 Vaccine protocol calls for two 100 µg doses.

A letter to the editor in the *New England Journal of Medicine* published February 17, 2021, showed vaccination with the Moderna COVID-19 Vaccine produced neutralizing titers against all key emerging variants tested, including B.1.1.7 and B.1.351, first identified in the UK and Republic of South Africa, respectively. The study showed no significant impact on neutralizing titers against the B.1.1.7 variant relative to prior variants. A six-fold reduction in neutralizing titers was observed with the B.1.351 variant relative to prior variants.

About the Moderna COVID-19 Vaccine

The Moderna COVID-19 Vaccine 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 the National Institute of Allergy and Infectious Diseases' (NIAID) 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 National Institutes of Health (NIH) on February 24, 2020, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of the Moderna COVID-19 Vaccine was dosed on March 16, 2020, 63 days from sequence selection to Phase 1 study dosing. On May 12, 2020, the U.S Food and Drug Administration granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, 2020, 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 the vaccine. On July 8, 2020, 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, 2020 in The New England Journal of Medicine. On July 28, 2020, 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, 2020, 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, 2020, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On November 30, 2020, the Company also announced that it filed for Emergency Use Authorization with the U.S. FDA and a Conditional Marketing Authorization (CMA) application with the

European Medicines Agency. On December 3, 2020, 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 U.S. FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. Moderna has also received authorization for its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore and Qatar. Additional authorizations are currently under review in other countries and by the World Health Organization.

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 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 purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.

Authorized Use

The 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. The Moderna COVID-19 Vaccine is investigational and is not approved by FDA.

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. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
- Available data on the 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 the 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 the Moderna COVID-19 Vaccine should receive a second dose of the 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

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Today, 24 development programs are underway across these therapeutic areas, with 13 programs having entered the clinic. 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 vaccines to protect against variants of the SARS-CoV-2 virus, which causes COVID-19; the Company's strategy for the development and testing of boosters, including multivalent boosters, to protect against COVID-19; the potential dosage for those vaccines; proposed clinical studies for evaluating these vaccines; the potential for these vaccines to protect against COVID-19; and potential regulatory approval for the Company's strategy for boosters and variant-specific vaccine candidates. 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; the Moderna COVID-19 Vaccine may prove less effective against variants of the SARS-CoV-2 virus, or the Company may be unsuccessful in developing future versions of its vaccine against these variants; 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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