Moderna Announces Submission of Initial Data to U.S. FDA for Its COVID-19 Vaccine Booster

September 1, 2021

mRNA-1273 at 50 µg dose level induced robust antibody responses of more than 40x against the Delta variant (B.1.617.2)

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 1, 2021-- Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced it has initiated its submission to the U.S. Food and Drug Administration (FDA) for the evaluation of a booster dose of the Moderna COVID-19 vaccine (mRNA-1273) at the 50 µg dose level. The Company expects to submit data to the European Medicines Agency (EMA) and other regulatory authorities around the world in the coming days.

"We are pleased to initiate the submission process for our booster candidate at the 50 µg dose with the FDA. Our submission is supported by data generated with the 50 µg dose of our COVID-19 vaccine, which shows robust antibody responses against the Delta variant," said Stéphane Bancel, Chief Executive Officer of Moderna. "We remain committed to staying ahead of the virus and following the evolving epidemiology of SARS-CoV-2. We will continue to generate data and transparently share to support governments and regulators as they make evidence-based decisions regarding future vaccination strategies."

The Phase 2 study of mRNA-1273 was amended to offer a booster dose of mRNA-1273 at the 50 µg dose level to interested participants 6 months following their second dose (n=344). Neutralizing antibody titers had waned significantly prior to boosting at approximately 6 months. A booster dose of mRNA-1273 at the 50 µg dose level boosted neutralizing titers significantly above the Phase 3 benchmark. After a third dose, a similar level of neutralizing titers was achieved across age groups, notably in older adults (ages 65 and above). The safety profile following dose 3 was similar to that observed previously for dose 2 of mRNA-1273. These data will be submitted to a peer-reviewed publication.

An additional analysis showed that a booster dose of mRNA-1273 at the 50 µg dose level induced robust antibody responses and significantly increased geometric mean titers (GMT) for all variants of concern including Beta (B.1.351) by 32- fold, Gamma (P.1) by 43.6-fold and Delta (B.1.617.2) by 42.3-fold.

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. 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 received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adults from health agencies in more than 50 countries and an Emergency Use Listing (EUL) from the World Health Organization (WHO).

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 Company's COVID-19 vaccine development efforts with 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.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with 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, 23 development programs are underway across these therapeutic areas, with 15 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.

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/clinical-considerations/managing-anaphylaxis.html).
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the

second dose.

- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- 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.
- The following adverse reactions have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials:
    - Severe allergic reactions, including anaphylaxis
    - Myocarditis and pericarditis
- 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.

Click for Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information for more information.

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 vaccine against COVID-19 (mRNA-1273); the Company’s submission to the U.S. FDA and other regulators for authorization to administer a third dose of mRNA-1273 at the 50 µg dose level; the ability of a third dose of mRNA-1273 at the 50 µg dose level to boost neutralizing antibody titers and to induce antibody responses against wildtype SARS-CoV-2 and variants of concern; and the safety profile for a third booster dose. 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 those other risks and uncertainties described under the heading “Risk Factors” in Moderna’s most recent Annual Report on Form 10-K 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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