Moderna Provides a Clinical Update on the Neutralizing Activity of its COVID-19 Vaccine on Emerging Variants Including the Delta Variant First Identified in India

June 29, 2021

Serum samples from eight participants obtained one week after second dose of the primary series in the Phase 1 clinical trial of the Moderna COVID-19 Vaccine

Serum neutralization assays performed on emerging variants including 2 additional versions of the Beta variant (B.1.351) and 3 lineage variants of B.1.617, including the Kappa (B.1.617.1) and Delta (B.1.617.2) variants

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 29, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced new results from in vitro neutralization studies of sera from individuals vaccinated with the Moderna COVID-19 Vaccine showing activity against variants of SARS-CoV-2. Vaccination with the Moderna COVID-19 Vaccine produced neutralizing titers against all variants tested, including additional versions of the Beta variant (B.1.351, first identified in South Africa), three lineage variants of B.1.617 (first identified in India), including the Kappa (B.1.617.1) and the Delta variants (B.1.617.2); the Eta variant (B.1.525, first identified in Nigeria); and the A.23.1 and A.VOI.V2 variants first identified in Uganda and Angola, respectively. These data were submitted as a preprint to *bioRxiv*.

"As we seek to defeat the pandemic, it is imperative that we are proactive as the virus evolves. We remain committed to studying emerging variants, generating data and sharing it as it becomes available. These new data are encouraging and reinforce our belief that the Moderna COVID-19 Vaccine should remain protective against newly detected variants," said Stéphane Bancel, Chief Executive Officer of Moderna. "These findings highlight the importance of continuing to vaccinate populations with an effective primary series vaccine."

The study methodology was previously described in the letter to the editor published in *NEJM* on April 15, 2021 concerning the variants first identified in the U.K. (Alpha, B.1.1.7) and the Republic of South Africa (Beta, B.1.351) using serum samples from eight participants obtained one week after participants' second dose of the primary series in the Phase 1 clinical trial of the Moderna COVID-19 Vaccine. These most recent data include neutralization assays against additional variant strains. This additional analysis showed minimal impact on neutralizing titers against the Alpha and A.23.1 variants relative to those against the ancestral strain (D614G). This analysis also showed a modest reduction in neutralizing titers against the Delta (2.1-fold), Gamma (P.1, 3.2-fold), Kappa (3.3-3.4-fold), and Eta (4.2-fold) variants relative to those against the ancestral strain. Consistent with previous results, a 7.3 or 8.4-fold reduction in neutralizing titers was observed with the additional versions of the Beta variant relative to the ancestral strain. Additionally, an 8.0-fold reduction in neutralizing titers relative to the ancestral strain was observed with A.VOI.V2, the variant first identified in Angola, but currently not designated as a Variant of Concern or Interest.

Moderna is pursuing a clinical development strategy against emerging variants to proactively address the pandemic as the virus continues to evolve. The Company is also studying mRNA-1273.211, a multivalent booster candidate which combines a 50-50 mix of mRNA-1273, Moderna's authorized vaccine against ancestral strains, and mRNA-1273.351 in a single vaccine at several dose levels in an ongoing study.

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). Moderna has filed for emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adolescents with health agencies in the European Union, Canada, the U.S., Switzerland and Japan.

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 autoimmune diseases. Today, 24 development programs are underway across these therapeutic areas, with 14 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).
- 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.
- Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials. In the post-authorization experience, very rare cases of myocarditis and pericarditis occurring in a mass vaccination setting have been reported.
- 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 efforts to develop a vaccine against COVID-19, as well as variants of the SARS-CoV-2 virus; the ability of these vaccine candidates to produce neutralizing titers and to confer protection against SARS-CoV-2 variants; the necessity of booster vaccinations against SARS-CoV-2; and the Company’s clinical development strategy for future booster candidates. 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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