



Moderna Announces TeenCOVE Study of its COVID-19 Vaccine in Adolescents Meets Primary Endpoint and Plans to Submit Data to Regulators in Early June

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Primary endpoint of non-inferior immunogenicity versus the Phase 3 study adult comparator group was met

No cases of COVID-19 observed after two doses of vaccine using the primary case definition, consistent with a vaccine efficacy of 100%

Safety and tolerability generally consistent with Phase 3 COVE study in adults; no significant safety concerns identified

Company plans to submit data to regulators globally in early June

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 25, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the Phase 2/3 study of its COVID-19 vaccine (mRNA-1273) in adolescents has met its primary immunogenicity endpoint, successfully bridging immune responses to the adult vaccination. In the study, no cases of COVID-19 were observed in participants who had received two doses of the Moderna COVID-19 vaccine using the primary definition. In addition, a vaccine efficacy of 93% in seronegative participants was observed starting 14 days after the first dose using the secondary CDC case definition of COVID-19, which tested for milder disease. This study, known as the TeenCOVE study, enrolled more than 3,700 participants ages 12 to less than 18 years in the U.S. The Company plans to submit these data to regulators globally in early June.

"We are encouraged that mRNA-1273 was highly effective at preventing COVID-19 in adolescents. It is particularly exciting to see that the Moderna COVID-19 vaccine can prevent SARS-CoV-2 infection," said Stéphane Bancel, Chief Executive Officer of Moderna. "We will submit these results to the U.S. FDA and regulators globally in early June and request authorization. We remain committed to doing our part to help end the COVID-19 pandemic."

In this Phase 2/3 study, 3,732 adolescent participants ages 12 to less than 18 years were enrolled and randomized 2:1 to two 100 µg doses of mRNA-1273 or placebo. The primary endpoint of non-inferior immunogenicity versus the Phase 3 adult study comparator group was met. After two doses, no cases of COVID-19 were observed in the vaccine group using the case definition from the adult Phase 3 COVE study, compared to 4 cases in the placebo group, resulting in a vaccine efficacy of 100% starting 14 days after the second dose. Because the incidence rate of COVID-19 is lower in adolescents, a secondary case definition based on the CDC definition of COVID-19 was also evaluated to include cases presenting with milder symptoms. Using the CDC definition, which requires only one COVID-19 symptom and a nasopharyngeal (NP) swab or saliva sample positive for SARS-CoV-2 by RT-PCR, a vaccine efficacy of 93% after the first dose was observed.

mRNA-1273 was generally well tolerated with a safety and tolerability profile generally consistent with the Phase 3 COVE study in adults. No significant safety concerns have been identified to date. The majority of adverse events were mild or moderate in severity. The most common solicited local adverse event was injection site pain. The most common solicited systemic adverse events after the second dose of mRNA-1273 were headache, fatigue, myalgia and chills.

Safety data continues to accrue, and the study continues to be monitored by an independent safety monitoring committee. All participants will be monitored for 12 months after their second injection to assess long-term protection and safety. Consequently, these data are subject to change based on ongoing data collection. The Company plans to submit data from the TeenCOVE study to a peer-reviewed publication.

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. FDA granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, 2020, the first participants in each age cohort 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 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 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 emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the Philippines, Thailand, Brunei, Paraguay, Japan, South Korea 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, 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.

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 its vaccine (mRNA-1273) against COVID-19; mRNA-1273's efficacy in adolescents and its ability to prevent infection or mitigate symptoms of COVID-19 in adolescents; the safety profile for mRNA-1273 in adolescents; and the Company's plans to seek regulatory approval for the administration of mRNA-1273 to adolescents in the U.S. and other jurisdictions. 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 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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