# Moderna Files for Conditional Marketing Approval for its COVID-19 Vaccine in Adolescents in the European Union

June 7, 2021

*Submission based on Phase 2/3 study of mRNA-1273 in adolescents ages 12 to less than 18 in the U.S.*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 7, 2021-- Moderna, Inc., (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has submitted for a conditional marketing approval (CMA) for its COVID-19 vaccine in adolescents with the European Medicines Agency (EMA).

"We are pleased to announce that we have submitted for conditional marketing approval of our COVID-19 vaccine with the European Medicines Agency for use in adolescents in the European Union," said Stéphane Bancel, Chief Executive Officer of Moderna. "We are encouraged that the Moderna COVID-19 vaccine was highly effective at preventing COVID-19 and SARS-CoV-2 infection in adolescents. We have filed for authorization with Health Canada and we will file for an Emergency Use Authorization with the U.S. FDA and regulatory agencies around the world for this important younger age population. We remain committed to doing our part to help end the COVID-19 pandemic."

In May, the Company announced that the Phase 2/3 TeenCOVE study of Moderna's COVID-19 vaccine in adolescents 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. The vaccine efficacy in the nearly 2,500 adolescents who received the Moderna COVID-19 vaccine was observed to be 100% when using the same case definition as in the Phase 3 COVE study in adults. In addition, a vaccine efficacy of 93% in seronegative participants was observed starting 14 days after the first dose using the secondary Centers for Disease Control and Prevention (CDC) case definition of COVID-19, which tested for milder disease. The study enrolled 3,732 participants ages 12 to less than 18 years in the U.S.

The Moderna COVID-19 vaccine 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. These data are subject to change based on ongoing data collection.

The Company also plans to submit for an emergency use authorization (EUA) with the U.S. Food and Drug Administration (FDA) to expand the authorized use of its vaccine to adolescents. Moderna has received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adults from health agencies in the U.S., Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the Philippines, Thailand, Brunei, Paraguay, Japan, South Korea, Botswana and an Emergency Use Listing (EUL) from the World Health Organization (WHO).

**About the COVID-19 Vaccine Moderna**

The COVID-19 Vaccine Moderna (referred to in the U.S. as 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, 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, 63 days from sequence selection to Phase 1 study dosing. On May 12, the U.S Food and Drug Administration 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 the vaccine. On July 8, the Phase 2 study completed enrolment.

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 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 received emergency (or other conditional, interim or provisional) authorization for use of its COVID-19 vaccine in adults from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, the Philippines, Thailand, Brunei, Paraguay, Japan, South Korea, Botswana and an Emergency Use Listing (EUL) from the World Health Organization (WHO).

Initial data from Moderna's Phase 2 study in the U.S. showed that a single 50 µg dose of mRNA-1273 or mRNA-1273.351 given as a booster to previously vaccinated individuals increased neutralizing antibody titer responses against SARS-CoV-2 and two variants of concern, B.1.351 (first identified in South Africa) and P.1 (first identified in Brazil). A booster dose of mRNA-1273.351, the Company's strain-matched booster, achieved higher neutralizing antibody titers against the B.1.351 variant of concern than a booster dose of mRNA-1273. Safety and tolerability profiles following third dose booster injections of 50 µg of mRNA-1273 or mRNA-1273.351 were generally comparable to those observed after the second dose of mRNA-1273 in the previously reported Phase 2 and Phase 3 studies. A manuscript describing these preliminary results was submitted as a preprint to *medRxiv* and will be submitted for peer-reviewed publication upon completion of the multivalent mRNA-1273.211 booster arm.

**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 regarding: the Company's development of a vaccine to protect against the SARS-CoV-2 virus (mRNA-1273, also referred to as COVID-19 Vaccine Moderna and the Moderna COVID-19 Vaccine); the Company's plans to file for Conditional Marketing Authorization with the EMA for the use of the vaccine by adolescents; the efficacy of the vaccine, and its safety profile. 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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