



Moderna Announces Emergency Use Listing Granted by the World Health Organization for its COVID-19 Vaccine

April 30, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 30, 2021-- [Moderna Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the World Health Organization (WHO) has issued Emergency Use Listing (EUL) for its COVID-19 vaccine to prevent COVID-19 in individuals 18 years of age and older.

"We thank the WHO for their data review and for their issuance of an Emergency Use Listing for our COVID-19 vaccine. We are actively participating in discussions with multilateral organizations, such as COVAX, to help protect populations around the world," said Stéphane Bancel, Chief Executive Officer of Moderna. "This EUL is an incredible step forward as we continue our quest to ensure that people on every continent have access to our mRNA vaccine so that we can defeat the devastating COVID-19 pandemic."

The EUL process assesses novel health products during public health emergencies with the goal of making medicines, vaccines and/or diagnostics available to address the emergency while adhering to stringent criteria of safety, efficacy and quality. The EUL pathway involves an assessment of late-stage clinical trial data as well as data on safety, efficacy and quality by independent experts and WHO teams.

The EUL also allows many countries around the world to expedite their own regulatory approval processes to import and administer a vaccine. It also enables UNICEF and the PAHO Revolving Fund to acquire the vaccine for distribution to countries in need. An EUL is a prerequisite to supply vaccines to the new COVAX Facility, a global mechanism for pooled procurement and distribution of COVID-19 vaccines in participating countries, including lower-income countries.

The WHO based its decision on the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study [announced](#) on November 30, 2020. Moderna will continue to share data with the WHO as it becomes available.

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 also received authorization for its COVID-19 vaccine from health agencies in Canada, Israel, the European Union, the United Kingdom, Switzerland, Singapore, Qatar and Taiwan. Additional authorizations are currently under review in other countries.

Preclinical data on the Company's variant-specific booster vaccine candidates have been submitted as a preprint to [bioRxiv](#) and will be submitted for peer-reviewed publication. These variant-specific vaccine candidates include mRNA-1273.351, which is more specifically targeted against the SARS-CoV-2 variant known as B.1.351 first identified in the Republic of South Africa, and 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. The Company's Phase 2 study to evaluate three [approaches to boosting](#) is ongoing.

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 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 a vaccine (mRNA-1273) to protect against the SARS-CoV-2 virus, which causes

COVID-19; the Company's discussions with COVAX and other countries for the supply of its COVID-19 vaccine; the process for the receipt of regulatory approval for distribution of the vaccine following receipt of an Emergency Use Listing from the World Health Organization; and the conduct of clinical trials 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 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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