



Moderna Provides Storage Update & Announces the U.S. FDA Authorizes Up To 15-Doses Per Vial of its COVID-19 Vaccine

April 2, 2021

U.S. EUA label allows for vaccine vials to remain at room temperature conditions for a longer period (total of 24 hours from previous 12 hours)

Label update also allows for two vial presentations (maximum of 15 doses and maximum of 11 doses)

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 1, 2021-- [Moderna, Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that based on submitted stability data, the U.S. Food and Drug Administration (FDA) has authorized the Moderna COVID-19 Vaccine to be kept at room temperature conditions once removed from the refrigerator for administration for 24 hours, an increase from the previous 12 hours. Additionally, a punctured vial is now useable for up to 12 hours, an increase from the previous 6 hours. These new guidelines are reflected in an updated Emergency Use Authorization (EUA) label. The Moderna COVID-19 Vaccine is ready for use and does not need to be diluted.

The FDA also authorized inclusion of a new vial presentation with a maximum of 15 doses of its COVID-19 vaccine. In parallel, the FDA also authorized a maximum of 11 doses of its COVID-19 vaccine in the current format, from the previously authorized 10 doses per vial. The Moderna COVID-19 Vaccine now can be supplied in two vial presentations (a multiple-dose vial containing a maximum of 11 doses or a multiple-dose vial containing a maximum of 15 doses). The Company expects that the 15-dose vials will begin shipping in the coming weeks.

"We are committed to constantly learning and improving to facilitate easier administration of our COVID-19 vaccine for medical staff and accelerate immunization programs. Thank you to the U.S. FDA and CDC for their ongoing collaboration," said Stéphane Bancel, Chief Executive Officer of Moderna. "We remain focused on doing all that we can to help end the COVID-19 pandemic with a vaccine."

Moderna is continually learning, adapting and working closely with its partners and the U.S. government to identify ways to facilitate accelerated vaccine administration, address bottlenecks and accelerate production. One identified constraint on the production process has been the capacity of the fill-and-finish process. Moderna studied the possibility of adding more doses to each vial of vaccine to address bottlenecks, accelerate production and reduce the need for consumable materials that are in high demand. Moderna will continue to collaborate with its manufacturing partners and the federal government to increase the efficiency of its production process without compromising quality or safety.

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

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.

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.
- 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 statements regarding: the Company’s development of a vaccine (mRNA-1273) to protect against the SARS-CoV-2 virus, which causes COVID-19; the conditions under which the vaccine can be stored and administered; the number of doses that can be included in each vial; the timing for shipments of vials containing 15 doses; and ongoing improvements to the process for manufacturing and shipping the vaccine. 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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