



Moderna Announces FDA Advisory Committee Unanimously Votes in Support of Emergency Use for a Booster Dose of Moderna's COVID-19 Vaccine in the U.S.

October 14, 2021

Positive unanimous vote for mRNA-1273 booster at the 50 µg dose level for individuals aged 65 and older as well as individuals aged 18 through 64 at high risk of contracting COVID-19 at least 6 months after completion of the primary series

Company estimates that booster at the 50 µg dose level could result in up to 1 billion additional doses

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 14, 2021-- [Moderna Inc.](#) (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today confirmed that the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended that the FDA grant an Emergency Use Authorization (EUA) for a booster dose of the Moderna COVID-19 vaccine (mRNA-1273) at the 50 µg dose level for people aged 65 and older; people aged 18 to 64 who are at high risk of severe COVID-19; and people aged 18 to 64 whose exposure to COVID-19 puts them at risk for COVID-19 complications or severe illness. The positive vote was unanimous with 19 VRBPAC members recommending EUA. The booster dose is to be administered at least six months after completion of the primary series.

"We are grateful for the opportunity to present the clinical data package for our COVID-19 booster vaccine to the FDA's advisory committee today. We thank the committee for their review and for their positive recommendation in support of Emergency Use Authorization. This positive recommendation is supported by data on the 50 µg booster dose of our COVID-19 vaccine, which shows robust antibody responses against the original virus, but also against the Delta variant," said Stéphane Bancel, Chief Executive Officer of Moderna. "We remain committed to staying ahead of the virus and following the evolving epidemiology of SARS-CoV-2. We look forward to making our booster available to people in the U.S. to help protect themselves against this ongoing public health emergency."

The VRBPAC based its recommendation on the totality of scientific evidence, including a data analysis from the Phase 2 clinical study of mRNA-1273, which was amended to offer a booster dose of mRNA-1273 at the 50 µg dose level to interested participants 6-8 months following their second dose (n=344). Neutralizing antibody titers had waned prior to boosting, particularly against variants of concern, at approximately 6 months. Notably, a booster dose of mRNA-1273 at the 50 µg dose level boosted neutralizing titers significantly above the Phase 3 benchmark. After a booster dose, a similar level of neutralizing titers was achieved across age groups, notably in older adults (ages 65 and above). The safety profile following the booster dose was similar to that observed previously for dose 2 of mRNA-1273.

Moderna estimates that the positive vote in support of mRNA-1273 at the 50 µg dose level and subsequent approval could result in up to 1 billion extra doses being available for distribution in 2022.

FDA advisory committees provide non-binding recommendations. The FDA will take the VRBPAC's recommendation into consideration in making a final decision on authorization. Under an EUA, the FDA has the authority to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions during a declared public health emergency when there are no adequate, approved, and available alternatives. Next, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet to discuss their recommendation for the use of COVID-19 boosters.

Separately, on August 13, Moderna announced that the U.S. FDA approved an update to the emergency use authorization for the Moderna COVID-19 vaccine to include a third dose at the 100 µg dose level for immunocompromised individuals 18 years of age or older in the United States who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

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. Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit www.modernatx.com.

AUTHORIZED USE IN THE US

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 the 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>).
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- 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 clinical trials 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.
- The following adverse reactions have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials:
 - Severe allergic reactions, including anaphylaxis
 - Myocarditis and pericarditis
 - Syncope
- Available data on the 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 the 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 the Moderna COVID-19 Vaccine should receive a second dose of the 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 development of a vaccine against COVID-19 (mRNA-1273); the potential for FDA approval of boosters at the 50 µg dose level for mRNA-1273, and the impact on the Company's vaccine production capacity for 2022; the potential for 50 µg booster doses to trigger an antibody response across different age groups; and the safety profile for the 50 µg booster doses of mRNA-1273. 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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