



Moderna Announces FDA Authorization of a Booster Dose of Moderna's COVID-19 Vaccine in the U.S.

October 20, 2021

Emergency Use Authorization (EUA) granted for individuals 65 years of age and older, and individuals ages 18 through 64 within certain high-risk groups

FDA also authorized the use of Moderna's booster dose following primary vaccination with other authorized or approved COVID-19 vaccines

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 20, 2021-- [Moderna Inc.](#) (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the U.S. Food and Drug Administration (FDA) has authorized for emergency use 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 with frequent institutional or occupational exposure to SARS-CoV-2. The booster dose is to be administered at least six months after completion of the primary series. The FDA also authorized a single booster dose of the Moderna COVID-19 Vaccine for individuals who have completed a primary vaccination with other authorized or approved COVID-19 vaccines.

"This emergency use authorization is supported by robust clinical evidence that a 50 µg booster dose induces a strong immune response against COVID-19. We thank the FDA for their review and for this EUA including for those people who have completed a primary vaccination with a different COVID-19 vaccine," said Stéphane Bancel, Chief Executive Officer of Moderna. "We believe that mRNA vaccines are uniquely positioned to adapt to the evolving epidemiology of SARS-CoV-2. We're grateful for the opportunity to provide individuals with another layer of protection."

The FDA based this EUA on the totality of scientific evidence shared by the company and [reviewed](#) by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), 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 including 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. The positive vote was unanimous with 19 VRBPAC members recommending EUA.

As a next step, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet to discuss a potential recommendation for the use and rollout of COVID-19 boosters to Americans.

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, and rash.
- Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.
- 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.
- 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 approval of mRNA-1273 for use as a booster dose; the ability of mRNA-1273 boosters at the 50 µg dose to trigger an immune response, and the safety profile for those boosters. 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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