



NEWS RELEASE

Moderna Files FDA Application for the JN.1 Targeting COVID-19 Vaccine

6/7/2024

Manufacturing is underway and doses of Moderna's Spikevax 2024-2025 formula will be ready to ship as early as August, pending regulatory approval

CAMBRIDGE, MA / ACCESSWIRE / June 7, 2024 / Moderna, Inc. (NASDAQ:MRNA) today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) for review of its Spikevax 2024-2025 formula, targeting the SARS-CoV-2 variant JN.1.

"For four years, Moderna has consistently delivered vaccines that offer protection against COVID-19, and work is well underway to provide a vaccine targeting JN.1," said Stéphane Bancel, CEO of Moderna. "Staying up to date with your COVID-19 vaccine remains one of the best ways to protect yourself during the upcoming respiratory illness season."

The submission is based on guidance from the U.S. FDA, which advised that COVID-19 vaccines should be updated to a monovalent JN.1 composition for the 2024-2025 season. This guidance aligns with the **recommendations** from the World Health Organization (WHO) Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) and the European Medicines Agency's Emergency Task Force (ETF) on the use of a monovalent JN.1 lineage for COVID-19 vaccine antigen composition.

The most common solicited local adverse event for Moderna's updated COVID-19 vaccine was injection site pain. The most common solicited systemic adverse events include headache, fatigue, myalgia and chills.

Moderna is submitting data to regulators worldwide to support registration and supply of the 2024-2025 formula of Spikevax in time for the upcoming vaccination season.

About Moderna

Moderna is a leader in the creation of the field of mRNA medicine. Through the advancement of mRNA technology, Moderna is reimagining how medicines are made and transforming how we treat and prevent disease for everyone. By working at the intersection of science, technology and health for more than a decade, the company has developed medicines at unprecedented speed and efficiency, including one of the earliest and most effective COVID-19 vaccines.

Moderna's mRNA platform has enabled the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and autoimmune diseases. With a unique culture and a global team driven by the Moderna values and mindsets to responsibly change the future of human health, Moderna strives to deliver the greatest possible impact to people through mRNA medicines. For more information about Moderna, please visit **modernatx.com** and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

AUTHORIZED USE IN THE U.S.

Emergency uses of the Moderna COVID-19 Vaccine (2023-2024 Formula) have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) for use in individuals 6 months through 11 years of age.

INDICATION (U.S.)

SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not administer SPIKEVAX to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of SPIKEVAX.

Warnings and Precautions

- Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of SPIKEVAX.
- Myocarditis and Pericarditis: Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. The observed risk is highest in males 18 years through 24 years of age.
- Syncope (fainting): May occur in association with administration of injectable vaccines, including SPIKEVAX. Procedures should be in place to avoid injury from fainting.
- Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to SPIKEVAX.
- Limitations of Vaccine Effectiveness: SPIKEVAX may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported ($\geq 10\%$) adverse reactions following any dose in any indicated patient population were pain at the injection site, headache, fatigue, myalgia, chills, arthralgia, axillary swelling/tenderness, nausea/vomiting, swelling at the injection site, erythema at the injection site, and fever.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967.

Please see the SPIKEVAX **Full Prescribing Information**.

Please see the Moderna COVID-19 Vaccine (2023-2024 Formula) **Fact Sheet for Healthcare Providers Administering Vaccine** 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: Moderna's regulatory submission to the U.S. FDA for its Spikevax 2024-2025 formula, including the potential for approval; Moderna's ability to supply its updated vaccine for the U.S. 2024 fall vaccination campaign; and Moderna's submissions to regulators worldwide and its ability to supply in time for 2024-2025 vaccination campaigns. 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, those risks and uncertainties described under the heading "Risk Factors" in Moderna's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and in subsequent filings made by Moderna with the U.S. Securities and Exchange Commission, 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 of this press release.

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