



NEWS RELEASE

EMA Committee for Medicinal Products for Human Use Adopts Positive Opinion Recommending Authorization of Moderna's COVID-19 mRNA Vaccine Targeting the SARS-CoV-2 Variant JN.1

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Moderna's updated COVID-19 mRNA vaccine will be available for the 2024-2025 vaccination season, pending a European Commission authorization decision

CAMBRIDGE, MA / ACCESSWIRE / September 5, 2024 / Moderna, Inc. (NASDAQ:MRNA) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending marketing authorization for an updated formulation of the COVID-19 mRNA vaccine Spikevax, targeting the SARS-CoV-2 variant JN.1, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals six months of age and older. Following the CHMP's positive opinion, the European Commission will make an authorization decision on the use of Moderna's updated COVID-19 vaccine for the autumn/winter season 2024-2025.

"The CHMP's positive recommendation for our updated COVID-19 mRNA vaccine targeting the SARS-CoV-2 variant JN.1 is a key milestone, demonstrating our commitment to protecting citizens across the European Union," said Stéphane Bancel, Chief Executive Officer of Moderna. "As respiratory diseases increase during the winter months, it is crucial for people to protect themselves by getting vaccinated with an updated COVID-19 vaccine that provides enhanced neutralizing antibody responses to JN.1 and its descendant lineages."

The CHMP decision is based on a combination of manufacturing and preclinical data, as well as previous clinical,

non-clinical, and real-world evidence supporting the efficacy and safety of Moderna's COVID-19 mRNA vaccines. The updated vaccine composition is based on guidance from the EMA's Emergency Task Force (ETF) in April 2024, which **recommended** that COVID-19 vaccines be updated to target the JN.1 family of Omicron subvariants for the 2024-2025 vaccination campaign. The EMA confirmed this recommendation in **July 2024**.

Moderna has received approval for its COVID-19 mRNA vaccine targeting the SARS-CoV-2 variant JN.1 in Japan, Taiwan, and the UK. In the U.S., Moderna has received approval for its COVID-19 vaccine targeting the KP.2 variant of SARS-CoV-2. Additional regulatory applications for Moderna's updated COVID-19 vaccines targeting KP.2 or JN.1 are under review by other regulatory agencies.

In the European Union, Moderna is participating in a tendering procedure for mRNA COVID-19 vaccines by the Health Emergency Preparedness and Response Authority (HERA) of the European Commission (EC).

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](https://www.modernatx.com)** and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

Moderna 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 potential authorization by the European Commission of Moderna's updated JN.1-targeting COVID-19 vaccine for autumn/winter 2024; the availability of Moderna's JN.1-targeting COVID-19 vaccine; and the ability of Moderna's updated COVID-19 vaccine to induce an immune response against circulating variants and provide protection for autumn/winter 2024. 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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