

Novavax Submits Application to European Medicines Agency for Updated Protein-based 2024-2025 Formula COVID-19 Vaccine

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- *Novavax's JN.1 COVID-19 vaccine is active against current circulating strains, including KP.2 and KP.3*

GAITHERSBURG, Md., June 24, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that it has filed for a type II variation of existing Marketing Authorization with the European Medicines Agency (EMA) for its JN.1 COVID-19 vaccine (NVX-CoV2705) for individuals aged 12 and older. The submission is in line with guidance from EMA and the [World Health Organization](#) to target the JN.1 lineage this fall.^{1,2}

"Novavax is working closely with European markets seeking to offer a protein-based alternative to mRNA this fall for COVID-19 vaccination," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Our updated COVID-19 vaccine is active against current circulating strains, including KP.2 and KP.3."

Nonclinical data have demonstrated that Novavax's JN.1 COVID-19 vaccine induces broad neutralization responses to JN.1 lineage viruses, including those containing the F456L and R346T mutations, and to "FLiRT" and "FLuQE" variants.²⁻⁴ Novavax's vaccine also produces conserved polyfunctional, Th1-biased CD4+ T cell responses to a range of JN.1 lineage variants.² Novavax's JN.1 COVID-19 vaccine targets the "parent strain" of KP.2 and KP.3.²

Novavax intends to have its vaccine in unit-dose vials available for distribution in the European Union for immediate release post-approval. Novavax has also [filed](#) with the U.S. Food and Drug Administration (FDA) and is working with other regulatory authorities globally on authorization or approval of its JN.1 COVID-19 vaccine.

About the Novavax COVID-19 2024-2025 Formula (NVX-CoV2705)

NVX-CoV2705 is an updated version of Novavax's prototype COVID-19 vaccine (NVX-CoV2373) formulated to target the JN.1 variant. It is a protein-based vaccine made by creating copies of the surface spike protein of SARS-CoV-2 that causes COVID-19. With Novavax's unique recombinant nanoparticle technology, the non-infectious spike protein serves as the antigen that primes the immune system to recognize the virus, while Novavax's Matrix-M adjuvant enhances and broadens the immune response. The vaccine is packaged as a ready-to-use liquid formulation and is stored at 2° to 8°C, enabling the use of existing vaccine supply and cold chain channels.

About Matrix-M™ Adjuvant

When added to vaccines, Novavax's patented saponin-based Matrix-M adjuvant enhances the immune system response, making it broader and more durable.⁵ The Matrix-M adjuvant stimulates the entry of antigen-presenting cells at the injection site and enhances antigen presentation in local lymph nodes.

About Novavax

Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to help protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, Md., U.S., offers a differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. The Company's portfolio includes its COVID-19 vaccine and its pipeline includes a vaccine for COVID-19 and influenza combined. In addition, Novavax's adjuvant is included in the University of Oxford and Serum Institute of India's R21/Matrix-M malaria vaccine. Please visit [novavax.com](#) and [LinkedIn](#) for more information.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the immunogenic response of its vaccine technology against variant strains and the scope, timing and outcome of future regulatory filings and actions, including any EMA or FDA recommendations, the intention to be ready to deliver a JN.1 protein-based COVID-19 vaccine this fall, are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, antigenic drift or shift in the SARS-CoV2 spike protein, challenges satisfying, alone or together with partners, various safety, efficacy and product characterization requirements, including those

related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges or delays in obtaining regulatory authorization for a JN.1 protein-based COVID-19 vaccine or for future COVID-19 variant strain changes; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov and www.novavax.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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