Novavax Submits Application to U.S. FDA for Updated Protein-based 2024-2025 Formula COVID-19 Vaccine

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- *Novavax's updated JN.1 COVID-19 vaccine is active against current circulating strains, including KP.2 and KP.3*
- *Novavax's JN.1 COVID-19 vaccine would be the only protein-based option available in the U.S.*
- *Novavax's filing is aligned with FDA, EMA and WHO global recommendations on vaccine composition*
- *Novavax intends to have its vaccine in pre-filled syringes available in the U.S. for immediate release post-authorization and following recommendation by the U.S. CDC*

GAITHERSBURG, Md., June 14, 2024/PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that it has submitted an amendment to its Emergency Use Authorization to the U.S. Food and Drug Administration (FDA) for its updated JN.1 COVID-19 vaccine (NVX-CoV2705) for individuals aged 12 and older. The submission is in line with guidance from the U.S. FDA, European Medicines Agency (EMA) and the World Health Organization (WHO) to target the JN.1 lineage this fall.[1-3]

Novavax's JN.1 vaccine has demonstrated broad cross-neutralizing antibodies against multiple variant strains, including KP.2 and KP.3, indicating the potential to protect against forward drift variants. As discussed at the recent FDA Vaccines and Related Biological Products Advisory Committee meeting, there is a public health benefit to target JN.1, the parent strain of the most common currently circulating variants.

"Novavax is committed to having a protein-based COVID-19 option available at the start of the vaccination season, which is critical because research suggests that providing vaccine choice, along with healthcare provider recommendations, may help improve vaccination rates," said John C. Jacobs, President and Chief Executive Officer, Novavax.

Nonclinical data have demonstrated that Novavax's JN.1 vaccine induces broad neutralization responses to JN.1 lineage viruses including those containing the F456L and R346T mutations, and to "FLiRT" and "FLuQE" variants.[2,4,5] Novavax's vaccine also produces conserved polyfunctional, Th1-biased CD4+ T cell responses to a range of JN.1 lineage variants.[2] Novavax's updated JN.1 COVID-19 vaccine targets the "parent strain" of KP.2 and KP.3.[2]

Novavax intends to have doses in the U.S. for distribution by mid-July. Upon FDA authorization and U.S. Centers for Disease Control and Prevention (CDC) recommendation, Novavax is preparing to promptly deliver to U.S. customers. Novavax is also 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. 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 CIC and stand-alone influenza vaccine candidates. 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 FDA or CDC recommendations, the intention to be ready to deliver a JN.1 protein-based non-mRNA COVID-19 vaccine by mid-August, 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 its product candidates, including an JN.1 protein-based non-mRNA 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; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; 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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