Novavax 2024-2025 Formula COVID-19 Vaccine Now Authorized and Recommended for Use in the U.S.

August 30, 2024

- *Novavax expects pre-filled syringes will be broadly available in thousands of locations across the U.S.*
- *Novavax's vaccine is the only protein-based option available in the U.S. for use in individuals aged 12 and older to prevent COVID-19*

GAITHERSBURG, Md., Aug. 30, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced the Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) (NVX-CoV2705) has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for active immunization to prevent COVID-19 in individuals aged 12 and older. Novavax's vaccine is included in the recommendations issued by the U.S. Centers for Disease Control and Prevention (CDC) on June 27, 2024.

Pre-filled syringes of the vaccine will be available in thousands of locations, including retail and independent pharmacies and regional grocers, following the Center for Biologics Evaluation and Research release of vaccine batches.

"Today's authorization enables Novavax to launch our updated COVID-19 vaccine in the U.S. in pre-filled syringes, and we have worked hard to ensure consumers have access in thousands of locations nationwide," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Our updated vaccine targets JN.1, the 'parent strain' of currently circulating variants, and has shown robust cross-reactivity against JN.1 lineage viruses, including KP.2.3, KP.3, KP.3.1.1 and LB.1."

In June, the CDC's Advisory Committee on Immunization Practices voted unanimously in favor of a universal recommendation for the use of 2024-2025 COVID-19 vaccines authorized under EUA or approved by Biologics License Application in individuals aged six months and older, regardless of specific viral strains.[1] As discussed at the June 2024 U.S. 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.[2,3] Novavax filed for JN.1 in line with guidance from the U.S. FDA, European Medicines Agency (EMA) and the World Health Organization to target the JN.1 lineage this fall.[2,4,5]

The EUA was based on non-clinical data that showed Novavax's updated vaccine provides cross-reactivity against JN.1 and numerous JN.1 lineage viruses, including KP.2.3, KP.3, KP.3.1.1 and LB.1.[1] In clinical trials, the most common adverse reactions associated with Novavax's prototype COVID-19 vaccine (NVX-CoV2373) included headache, nausea or vomiting, muscle pain, joint pain, injection site tenderness, injection site pain, fatigue and malaise.

AUTHORIZED USE IN THE U.S.
Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) has not been approved or licensed by the FDA but has been authorized for emergency use by the FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. Refer to the full Fact Sheet for information about the Novavax COVID-19 Vaccine, Adjuvanted.

The EUA of this product will remain in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the authorization is revoked sooner.

VACCINE AUTHORIZATION (U.S.)
Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) is 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 the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of the Novavax COVID-19 Vaccine, Adjuvanted.

- **Myocarditis and Pericarditis**: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted.
- **Syncope (fainting):** may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.
- **Limitations of Vaccine Effectiveness:** The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Adverse Reactions
Solicited adverse reactions included: Injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling 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, by calling 1-800-822-7967 or send an email to info@vaers.org.

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.[3] 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 COVID-19-Influenza Combination 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 EMA or FDA recommendations, the expectation to have pre-filled syringes broadly available in thousands of locations in the U.S., 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-CoV-2 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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SOURCE Novavax, Inc.