

# Novavax Prepared to Deliver Protein-based Monovalent XBB COVID Vaccine Consistent with FDA VRBPAC Recommendation for the Fall

June 15, 2023

- *Novavax has developed a protein-based monovalent XBB.1.5 COVID vaccine candidate and is manufacturing at commercial scale with the intent to be in market during the fall vaccination campaign*
- *Novavax shared data demonstrating that its XBB.1.5 COVID vaccine candidate induces functional immune responses to XBB subvariants including XBB.1.5, XBB.1.16 and XBB.2.3*
- *If authorized, Novavax's protein-based vaccine candidate would be the only non-mRNA XBB.1.5 vaccine available in the U.S.*
- *Novavax intends to supply vaccine globally, consistent with FDA, WHO and EMA recommendations*

GAITHERSBURG, Md., June 15, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its novel Matrix-M™ adjuvant, participated in today's U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee's (VRBPAC) meeting, which resulted in a unanimous vote recommending updating the current COVID vaccine composition to a monovalent XBB-lineage.

"Novavax expects to be ready for the commercial delivery of a protein-based monovalent XBB COVID vaccine this fall in line with today's VRBPAC recommendation," said John C. Jacobs, President and Chief Executive Officer, Novavax. "In partnership with regulators and public health authorities, Novavax has been developing and manufacturing this vaccine candidate, and now that we are nearing harmonization on guidance from the FDA, the World Health Organization and European Medicines Agency, we believe we are in a better position to offer an alternative vaccine choice for individuals worldwide."

Novavax presented data at the VRBPAC meeting that supports the recommendation to vaccinate this fall with a monovalent XBB strain. Novavax data showed that its XBB.1.5 COVID vaccine candidate induced functional immune responses for XBB.1.5, XBB.1.16 and XBB.2.3 variants, indicating a broad response that could potentially be applicable for forward-drift variants.

Novavax will seek updated FDA labeling for its XBB COVID vaccine candidate with the goal of it being available and accessible on par with other COVID vaccines.

## **Authorized Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.**

The Novavax COVID-19 Vaccine, Adjuvanted vaccine has not been approved or licensed by the U.S. FDA, but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) as a primary series in individuals 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted vaccine is also authorized to provide a first booster dose at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

## **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 to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted. Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate

adverse reactions according to the [Centers for Disease Control \(CDC\) and Prevention guidelines](#).

**Myocarditis and Pericarditis:** Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted (see Full EUA Prescribing Information). The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis>).

**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**

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, anaphylaxis, paresthesia, and hypoesthesia have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

### **Reporting Adverse Events and Vaccine Administration Errors**

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of myocarditis,
- cases of pericarditis,
- cases of Multisystem Inflammatory Syndrome (MIS), in adults and children, and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Novavax COVID-19 Vaccine, Adjuvanted EUA" in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: [www.NovavaxMedInfo.com](http://www.NovavaxMedInfo.com), Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

Please click to see the [Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) and EUA Full Prescribing Information](#).

Please click to see the [Fact Sheet for Recipients and Caregivers](#).

### **About Novavax**

Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to 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. Focused on the world's most urgent health challenges, Novavax is currently evaluating vaccines for COVID, influenza, and COVID and influenza combined. Please visit [novavax.com](http://novavax.com) and [LinkedIn](#) for more information.

### **Forward-Looking Statements**

Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-

CoV2373, XBB variant vaccines candidates, the scope, timing and outcome of future regulatory filings and actions, the potential impact and reach of Novavax and NVX-CoV2373 and its XBB variant candidates in addressing vaccine access, protecting populations, the efficacy, safety intended utilization, and the expected administration of NVX-CoV2373 and XBB vaccine candidates 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, 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; unanticipated challenges or delays in conducting clinical trials; 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, 2022 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](http://www.sec.gov) and [www.novavax.com](http://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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