Novavax's Updated Protein-based XBB COVID Vaccine Induced Neutralizing Responses Against Emerging Subvariants, Including EG.5.1 and XBB.1.16.6

August 22, 2023

- *Novavax's 2023-2024 season COVID vaccine candidate induced neutralizing responses to emerging subvariants EG.5.1 and XBB.1.16.6 in addition to XBB.1.5, XBB.1.16 and XBB.2.3*
- *Upon regulatory approval, Novavax's COVID vaccine would be the only protein-based non-mRNA vaccine option available in key markets for the fall season*

GAITHERSBURG, Md., Aug. 22, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its novel Matrix-M™ adjuvant, today announced that its updated protein-based XBB COVID vaccine candidate induced neutralizing antibody responses to the EG.5.1 and XBB.1.16.6 subvariants in small animal and non-human primate studies. XBB sublineage variants are overwhelmingly responsible for the majority of current COVID cases in the U.S. and European Union.[1, 2]

"Our data have shown that Novavax's protein-based COVID vaccine induces broadly neutralizing responses against XBB subvariants, including EG.5.1 and XBB.1.16.6," said Filip Dubovsky, President of Research and Development, Novavax. "We have a lot of confidence in our updated COVID vaccine and are working diligently with global regulatory bodies to ensure our protein-based vaccine is available this fall."

Non-clinical data previously showed that Novavax's 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.[3] Novavax is in the process of submitting applications for its XBB.1.5 COVID vaccine candidate to regulatory authorities globally.

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.

Authorized Use
The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series 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. 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.

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**, 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 and LinkedIn for more information.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its near term priorities including delivering an updated, COVID vaccine for the 2023 fall vaccination season, the scope, timing and outcome of future and pending regulatory filings and actions, including submissions of applications to global regulatory authorities , 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, assay validation, and stability testing, 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 conducting clinical trials or obtaining regulatory authorization for our product candidates, including for our monovalent XBB COVID vaccine in time for the fall 2023 vaccination season, or for future COVID variant strain changes; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; manufacturing, distribution, or export delays or challenges, including the requirement to obtain approval from the drug licensing body in India for the distribution of Novavax's updated XBB COVID vaccine; Novavax's exclusive dependence on Serum for co-formulation and filling, and PCI for finishing NVX-CoV2373 and the impact of any delays or disruptions in these suppliers' operations on the delivery of customer orders; challenges in implementing our global restructuring and cost reduction plan; 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 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.

Contacts:
Investors
Erika Schultz
240-268-2022
ir@novavax.com

Media
Ali Chartan
240-720-7804
media@novavax.com

References

1. Centers for Disease Control and Prevention (CDC). (2023). *Variant Proportions* [Data set]. In COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#variant-proportions.
2. European Centers for Disease Control and Prevention. (2023). *Country overview report: week 32 2023* [Virus variants]. https://www.ecdc.europa.eu/en/covid-19/country-overviews.
3. Markov PV, Ghafari M, Beer M, et al. The evolution of SARS-CoV-2. *Nat Rev Microbiol*. 2023;21(6):361-379. doi:10.1038/s41579-023-00878-2.

SOURCE Novavax, Inc.