Novavax's Nuvaxovid™ Receives Full Marketing Authorization in the EU for the Prevention of COVID

July 6, 2023

- *Marketing Authorization replaces conditional Marketing Authorization and is first for Novavax in the EU*
- *Marketing Authorization includes use of Nuvaxovid™ as a primary series in individuals aged 12 and older and booster in adults*
- *Marketing Authorization provides regulatory foundation for future vaccine updates, including Fall vaccination campaign*

GAITHERSBURG, Md., July 6, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its novel Matrix-M™ adjuvant, has been granted full Marketing Authorization (MA) by the European Commission in the European Union (EU) for Nuvaxovid™ (NVX-CoV2373). This decision follows positive opinion for a full MA from the Committee for Medicinal Products for Human Use of the European Medicines Agency. The vaccine is now fully authorized for use as a primary series in individuals aged 12 and older and as a booster dose in adults aged 18 and older for the prevention of COVID-19. Nuvaxovid was originally granted a conditional MA in the EU for these indications.

"This Marketing Authorization establishes the foundation for all future regulatory approvals for updated versions of our COVID vaccine, a necessity to ensure we can quickly get our vaccine to individuals in the EU," said John C. Jacobs, President and Chief Executive Officer, Novavax. "In addition to the EU, we are preparing to file for full approval in the U.S. as well as other markets and are committed to ensuring protein-based options are available worldwide. Vaccine choice remains an integral part of public health measures."

The Phase 3 PREVENT-19 trial demonstrated Nuvaxovid's reassuring safety profile as well as efficacy as a primary series in adults, the immunogenicity and safety as a booster dose in adults, and the efficacy and safety as a primary series in individuals aged 12 and older.

Novavax's COVID vaccine is authorized for use in more than 40 markets around the world.

Trade Name in the U.S.
The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA).

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**, 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 Nuvaxovid™ (NVX-CoV2373)
NVX-CoV2373 is a protein-based vaccine made by creating copies of the surface spike protein of SARS-CoV-2 that causes COVID. 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 the PREVENT-19 Phase 3 Trial
The PRE-fusion protein subunit?Vaccine?Efficacy?Novavax?Trial COVID-19 (PREVENT-19) was a randomized, placebo-controlled, observer-blinded Phase 3 trial conducted in the U.S. and Mexico to evaluate the efficacy and safety of NVX-CoV2373 as a primary series and as a booster in adults and adolescents to prevent SARS-CoV-2 infection. As a primary series, the primary endpoint was the first occurrence of polymerase chain reaction (PCR)-confirmed symptomatic (mild,

moderate, or severe) COVID-19 with onset at least seven days after the second dose in 29,960 adult participants aged 18 and older at baseline without protocol violations prior to illness. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Full results of the trial were published in *the New England Journal of Medicine* .

The pediatric expansion of the trial evaluated 2,247 adolescents aged 12 through 17 years in the U.S. Results from the expansion were announced in February 2022. The adult booster expansion of the trial evaluated a single booster dose of the vaccine in adult participants approximately six months after their primary two-dose vaccination series. Results from the expansion were announced in October 2022.

About Matrix-M™ Adjuvant
When added to vaccines, Novavax's patented saponin-based Matrix-M adjuvant enhances the immune system response, making it stronger, 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 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 operating plans and prospects, the ongoing development of NVX-CoV2373, NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a COVID-19-Influenza combination investigational vaccine candidate, a quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, , additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the evolving COVID-19 pandemic, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, protecting populations, the efficacy, safety intended utilization, and the expected administration of NVX-CoV2373 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** 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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