Novavax's Prototype COVID-19 Vaccine Nuvaxovid™ Receives Full Approval in Singapore

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GAITHERSBURG, Md., Oct. 18, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that Singapore's Health Sciences Authority (HSA) has granted full approval for Novavax's prototype COVID-19 vaccine Nuvaxovid™ (NVX-CoV2373) for active immunization to prevent COVID-19 in individuals aged 12 and older. The Singapore Ministry of Health has included Nuvaxovid in the National Vaccination Programme as a protein-based non-mRNA option for COVID-19 prevention.

"Today's full approval of our prototype vaccine will enable us to file for approval of our updated protein-based non-mRNA COVID-19 vaccine in the coming weeks," said John C. Jacobs, President and Chief Executive Officer, Novavax. "We continue to work closely with HSA to ensure a protein-based vaccine is part of the portfolio for Singaporeans to protect themselves against COVID-19."

For the 2023-2024 vaccination season, Novavax has developed an updated COVID-19 vaccine which has been authorized for use in the U.S. The updated vaccine induces neutralizing antibody responses against currently circulating variants XBB.1.5, XBB.1.16, XBB.2.3, BA.2.86, EG.5.1, FL.1.5.1 and XBB.1.16.6. Additional non-clinical data demonstrated that Novavax's vaccine induced CD4+ polyfunctional cellular (T-cell) responses against EG.5.1 and XBB.1.16.6. These data indicate Novavax's vaccine can stimulate both arms of the immune system and may induce a broad response against currently circulating variants.[1,2]

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.

Trade Name Use
The trade name Nuvaxovid™ has not been approved by the U.S. Food and Drug Administration.

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-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 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*.

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. Focused on the world's most urgent health

challenges, Novavax is currently evaluating vaccines for COVID-19, influenza and COVID-19 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 scope, timing and outcome of future regulatory filings and actions, including its coordination with HSA, 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; 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 its updated XBB version of its COVID-19 vaccine in time for the fall 2023 vaccination season 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 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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2. 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.

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