Novavax's Updated COVID-19 Vaccine Now Authorized in Canada

December 5, 2023

- *Novavax's updated protein-based non-mRNA COVID-19 vaccine will be available in Canada for individuals aged 12 and older in the coming days*

GAITHERSBURG, Md., Dec. 5, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that Health Canada has granted expanded authorization for Nuvaxovid™ XBB.1.5 Vaccine (Recombinant protein, Adjuvanted) (NVX-CoV2601) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged 12 and older. The Public Health Agency of Canada's National Advisory Committee on Immunization recommended XBB COVID-19 vaccines that target more recent, immune-evasive variants of the virus.[1]

"Today's expanded authorization will support the Canadian government's strong commitment to provide its citizens with effective options, such as our protein-based non-mRNA vaccine, in the campaign against currently circulating COVID-19 variants," said John C. Jacobs, President and Chief Executive Officer, Novavax. "We look forward to helping to protect Canadians in time for the upcoming holiday season and, pending vaccine batch release, have doses in market for access across the country."

The expanded authorization was based on non-clinical data showing that Novavax's COVID-19 vaccine induced functional immune responses against XBB.1.5, XBB.1.16 and XBB.2.3 variants. Additional non-clinical data demonstrated that Novavax's vaccine induced neutralizing antibody responses to subvariants BA.2.86, EG.5.1, FL.1.5.1 and XBB.1.16.6 as well as 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.[2,3]

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.

Novavax's updated COVID-19 vaccine is also authorized in the U.S., the European Union and by the WHO, and is under review in other markets.

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

About Nuvaxovid™ XBB.1.5 2023-2024 Formula (NVX-CoV2601)
NVX-CoV2601 is an updated version of Novavax's prototype COVID-19 vaccine (NVX-CoV2373) formulated to target the Omicron XBB.1.5 subvariant. 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. 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 the availability of its updated XBB version of its Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) (NVX-CoV2601) and the timing of vaccine batch release, delivery, and distribution of its vaccine 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; 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 filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; challenges in obtaining commercial adoption of our updated protein-based non-mRNA XBB COVID-19 vaccine, NVX-CoV2373 or any COVID-19 variant strain-containing formulation; 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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