Novavax Submits Application to Health Canada for Updated Protein-based 2024-2025 Formula COVID-19 Vaccine

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- *Novavax's COVID-19 vaccine would be the only protein-based option available in Canada, if authorized*
- *Novavax's filing is aligned with NACI, U.S. FDA, EMA and WHO recommendations on vaccine composition*

GAITHERSBURG, Md., July 2, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, announced that it has filed for authorization with Health Canada for its 2024-2025 Formula COVID-19 vaccine (NVX-CoV2705) for individuals aged 12 and older. The submission follows the National Advisory Committee on Immunization (NACI) guidance to use the latest selected strain and the guidance from the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and World Health Organization (WHO).[1-4]

"Novavax is working closely with Health Canada to have an updated protein-based COVID-19 vaccine option approved for all eligible Canadians this fall," said John C. Jacobs, President and Chief Executive Officer, Novavax. "Our updated COVID-19 vaccine is active against JN.1, KP.2 and KP.3, in addition to other JN.1 sublineage strains."

Nonclinical data have demonstrated that Novavax's updated COVID-19 vaccine induces broad neutralization responses to JN.1 lineage viruses, including those containing the F456L and R346T mutations, to "FLiRT" variants and to "FLuQE" variants such as KP.3.[4-6] Novavax's vaccine also produces conserved polyfunctional, Th1-biased CD4+ T cell responses to a wide range of JN.1 lineage variants.[4] These responses indicate that Novavax's vaccine technology induces broadly neutralizing responses against multiple variant strains, including responses to circulating forward drift variants.

Novavax intends to have its vaccine available in Canada for immediate release post-authorization, should public health programs choose to provide this option. Novavax has filed with the U.S. FDA and EMA, and is working with other regulatory authorities globally on authorization or approval of its updated COVID-19 vaccine.

About the Novavax COVID-19 2024-2025 Formula (NVX-CoV2705)
NVX-CoV2705 is an updated version of Novavax's prototype COVID-19 vaccine (NVX-CoV2373) formulated to target the JN.1 variant. 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.[7] 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. The Company's portfolio includes its COVID-19 vaccine and its pipeline includes a vaccine for influenza and COVID-19 and influenza combined. In addition, Novavax's adjuvant is included in the University of Oxford and Serum Institute of India's R21/Matrix-M malaria vaccine. 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 immunogenic response of its vaccine technology against variant strains and the scope, timing and outcome of future regulatory filings and actions, including any Health Canada, EMA or FDA recommendations, the timing of its delivery for a JN.1 protein-based COVID-19 vaccine this fall, 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, antigenic drift or shift in the SARS-CoV2 spike protein, 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 a JN.1 protein-based COVID-19 vaccine 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; 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, 2023, 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
Giovanna Chandler
240-720-7804
media@novavax.com

References

1. Public Health Agency of Canada. Guidance on the use of COVID-19 vaccines during the fall of 2024. May 5, 2024. Available at: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024
2. U.S. Food and Drug Administration. Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2024. June 13, 2024. Available at: https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2024
3. European Medicines Agency. ETF recommends updating COVID-19 vaccines to target new JN.1 variant. April 30, 2024. Available at: https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-jn1-variant
4. World Health Organization. Statement on the antigen composition of COVID-19 vaccines. April 26, 2024. Available at: https://www.who.int/news/item/26-04-2024-statement-on-the-antigen-composition-of-covid-19-vaccines
5. U.S. Centers for Disease Control and Prevention. Variant Proportions [Data set]. In COVID Data Tracker. 2024. Available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions
6. Focosi D, Spezia PG, Gueli F, Maggi F. The Era of the FLips: How Spike Mutations L455F and F456L (and A475V) Are Shaping SARS-CoV-2 Evolution. *Viruses*. 2023;16(1):3. Published 2023 Dec 19. doi:10.3390/v16010003.
7. Stertman L, Palm AE, Zarnegar B, et al. The Matrix-M™ adjuvant: A critical component of vaccines for the 21st century. *Hum Vaccin Immunother*. 2023;19(1):2189885. doi:10.1080/21645515.2023.2189885.