Novavax Initiates Phase 3 Trial for COVID-19-Influenza Combination and Stand-Alone Influenza

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- *Company continuing to work with the U.S. FDA on potential for accelerated approval pathway*
- *Novavax intends to partner on both candidates to advance to filing and commercialization*

GAITHERSBURG, Md., Dec. 10, 2024 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that the first participants have been dosed in its COVID-19-Influenza Combination (CIC) and stand-alone seasonal influenza Phase 3 trial. The trial will evaluate the immunogenicity and safety of the CIC and stand-alone seasonal influenza vaccine candidates compared to Novavax's updated 2024-2025 COVID-19 vaccine (NVX-CoV2705) and a licensed seasonal influenza vaccine comparator in adults aged 65 and older.

"A combination vaccine for two vaccine-preventable diseases is an important step forward for public health and the trial start is a key step in advancing our late-stage pipeline, which we plan to progress through strategic partnerships," said Ruxandra Draghia-Akli, MD, PhD, Executive Vice President, Head of Research and Development, Novavax. "Our goal is to get these assets to market as soon as possible, and we will work with the U.S. FDA to assess the possibility of an accelerated approval pathway."

The Company is working with the U.S. Food and Drug Administration (FDA) to determine the potential of the current CIC and stand-alone influenza trial to support accelerated approval. While in the process of seeking alignment on accelerated approval criteria with the U.S. FDA, Novavax has decided to recruit an initial cohort of approximately 2,000 participants while continuing this dialogue. Novavax anticipates being able to provide more clarity and information on potential next steps by Q2 2025, including if additional clinical work would be needed to achieve registration for these assets.

The randomized Phase 3 trial builds on positive Phase 2 data and aims to further evaluate the immunogenicity and safety of a combination of Novavax's updated 2024-2025 COVID-19 vaccine, trivalent nanoparticle stand-alone seasonal influenza vaccine candidate and patented saponin-based Matrix-M adjuvant relative to separate administrations of Novavax's updated 2024-2025 COVID-19 vaccine and a licensed seasonal influenza vaccine comparator. In addition, the trial also aims to further evaluate the immunogenicity and safety of Novavax's stand-alone influenza vaccine, also containing Matrix-M.

The Company's FY 2025 financial guidance for combined Research & Development and Selling, General and Administrative expense of approximately $500 million is inclusive of this CIC and stand-alone influenza initial planned Phase 3 clinical activity and is subject to revisions and updates as next steps are determined.

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 its CIC and stand-alone influenza vaccine candidates. 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, its updated combined annual Research & Development and Selling, General and Administrative expense target for FY 2025, the potential for its CIC and stand-alone influenza study to be used for accelerated approval and the timing of updates related thereto, 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 pursuing additional partnership opportunities; 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; challenges or delays in conducting clinical trials or studies for its product candidates; challenges or delays in obtaining regulatory

authorization for its product candidates, including for future COVID-19 variant strain changes, its CIC vaccine candidate, its stand-alone influenza vaccine candidate or other product candidates; manufacturing, distribution or export delays or challenges; Novavax's substantial dependence on Serum Institute of India Pvt. Ltd. and Serum Life Sciences Limited for co-formulation and filling Novavax's COVID-19 vaccine and the impact of any delays or disruptions in their operations; difficulty obtaining scarce raw materials and supplies including for its proprietary adjuvant; resource constraints, including human capital and manufacturing capacity; constraints on Novavax's ability to pursue planned regulatory pathways, alone or with partners; challenges in implementing its global restructuring and cost reduction plan; challenges in obtaining commercial adoption and market acceptance of its updated 2024-2025 formula COVID-19 vaccine or any COVID-19 variant strain containing formulation, or for its CIC vaccine candidate and stand-alone influenza vaccine candidate or other product candidates; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities, including requirements to deliver doses that may require Novavax to refund portions of upfront and other payments previously received or result in reduced future payments pursuant to such agreements and challenges in amending or terminating such agreements; challenges related to the seasonality of vaccinations against COVID-19; challenges related to the demand for vaccinations against COVID-19 or influenza; challenges in identifying and successfully pursuing innovation expansion opportunities; Novavax's expectations as to expenses and cash needs may prove not to be correct for reasons such as changes in plans or actual events being different than its assumptions; 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
Luis Sanay, CFA
240-268-2022
ir@novavax.com

Media
Giovanna Chandler
240-720-7804
media@novavax.com

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