Novavax Announces Initiation of Phase 2 Trial for COVID-19-Influenza Combination and Stand-Alone Influenza Vaccine Candidates

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GAITHERSBURG, Md., Dec. 30, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the initiation of a Phase 2 trial for its COVID-19-Influenza Combination (CIC) and influenza stand-alone vaccine candidates. The dose-confirming trial will evaluate the safety and effectiveness (immunogenicity) of different formulations of the CIC and influenza vaccine candidates in adults aged 50 through 80.

"We're encouraged by the initiation of this trial given the positive results shared earlier this year from our Phase 1/2 trial, the first of its kind to evaluate a combined COVID-19 and influenza vaccine," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We believe that like influenza, COVID-19 will also be seasonal moving forward, and that there is room in the market for new alternatives to provide better protection against the impact of influenza, particularly in older adults, and to explore the potential to combine this with protection from COVID."

The randomized, observer-blinded trial will assess a combination of Novavax' recombinant protein-based COVID-19 vaccine (NVX-CoV2373), quadrivalent influenza vaccine candidate, and patented saponin-based Matrix-M™ adjuvant. Primary and secondary objectives of the study are to assess the safety, tolerability, and immune responses to various formulations of the CIC and influenza vaccine candidates. The Phase 2 dose-confirmation trial will be conducted in two parts and seek to enroll a total of approximately 2,300 participants across multiple sites located in Australia and New Zealand.

Initial results of the trial are expected mid-year 2023. These data will inform the Phase 3 trials for both influenza stand-alone and COVID-19-influenza combination candidates.

About NVX-CoV2373
NVX-CoV2373 is a protein-based vaccine engineered from the genetic sequence of the first strain of SARS-CoV-2, the virus that causes COVID-19 disease. The vaccine was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

The vaccine is packaged as a ready-to-use liquid formulation and is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels. Use of the vaccine should be in accordance with official recommendations.

Novavax has established partnerships for the manufacture, commercialization, and distribution of NVX-CoV2373 worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India, the world's largest vaccine manufacturer by volume. They will later be supplemented with data from additional manufacturing sites throughout Novavax' global supply chain.

About Matrix-M™ Adjuvant
Novavax' patented saponin-based Matrix-M adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response.

About Novavax
Novavax, Inc. (Nasdaq: NVAX) is a biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. The company's proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. The Novavax COVID-19 vaccine, has received authorization from multiple regulatory authorities globally, including the U.S. FDA, the European Commission, and the World Health Organization. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its CIC vaccine candidate, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based

vaccine. These vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

For more information, visit **www.novavax.com** and connect with us on **LinkedIn**.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the timing of clinical trial results, the ongoing development of NVX-CoV2373, NVX-CoV2515 and a bivalent Omicron-based / original strain based vaccine, the CIC vaccine candidate, including Novavax' plans to initiate a Phase 3 study in 2024, a quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, increasing vaccination rates, controlling the pandemic, and protecting populations, the efficacy, safety, intended utilization, and expected administration of NVX-CoV2373 and the CIC vaccine candidate 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' Annual Report on Form 10-K for the year ended December 31, 2021 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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