Novavax Investor Relations

- *Trial is the first of its kind to evaluate a combined COVID-19 and influenza vaccine*
- *Dose insights from Phase 1/2 trial will inform Phase 2 confirmation trial to begin in late 2022*

GAITHERSBURG, Md., Oct. 13, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced positive results from the Phase 1/2 clinical trial of its COVID-19-Influenza Combination (CIC) vaccine candidate. Data demonstrated the CIC vaccine's ability to generate immune responses, including both antibody and polyfunctional CD4+ T-cell (lymphocytes that help coordinate the immune response) responses against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and homologous and heterologous influenza strains. The CIC combines Novavax' COVID-19 vaccine (NVX-CoV2373) and its quadrivalent influenza vaccine candidate.

The CIC vaccine formulations demonstrated induction of polyfunctional CD4+ T-cell responses against both SARS-CoV-2 and homologous and heterologous influenza strains at levels comparable to stand-alone NVX-CoV2373 and quadrivalent influenza vaccine candidate reference formulations. NVX-CoV2373 has previously been shown to induce functional SARS-CoV-2–specific CD4+ and CD8+ T-cell responses, and Novavax' quadrivalent influenza vaccine candidate has previously been shown to induce cross-reactive polyfunctional CD4+ T-cell responses. T-cell responses are thought to play an important role in the immune system's control of SARS-CoV-2 and influenza virus infections (e.g., by limiting disease severity and clearing infection), and in increasing the breadth of immunity.

The CIC vaccine formulations generated robust antibody responses against both SARS-CoV-2 and influenza antigens, and antibody responses were modelled using a Design of Experiments (DoE) approach to help optimize future dose selection.

The safety and tolerability profile of the CIC vaccine was consistent with the stand-alone NVX-CoV2373 prototype vaccine and quadrivalent influenza vaccine candidate reference formulations in the trial. The CIC vaccine was found to be generally well tolerated. Serious adverse events were rare, and none were assessed as being related to the vaccine.

"Today's results demonstrate that our COVID-19-Influenza Combination vaccine candidate is feasible, well-tolerated, and immunogenic, inducing both antibody and T-cell responses," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "As we transition from a SARS-CoV-2 pandemic to endemic circulation, we believe our protein-based combination vaccine candidate can help address two global public health threats with one vaccine."

"The DoE modeling approach in the trial enabled assessment of the optimal dose of both the COVID-19 and influenza antigens for further development of the COVID-19-Influenza Combination vaccine candidate," said Vivek Shinde, M.D., MPH, Vice President, Clinical Development Lead, Older Adult CIC, Influenza & RSV Vaccines, Novavax, who presented the results. "These preliminary results provide important insights on dose regimens that can be applied as we look to the Phase 2 confirmation trial later this year."

The DoE modeling-based approach used to design the trial enabled more powerful fine-tuning of dose selection of both the COVID-19 and influenza antigens for further development compared to traditional approaches. These dose insights will inform the Phase 2 confirmation trial to begin by the end of 2022.

Both protein-based vaccines used in the trial were formulated with Novavax' patented saponin-based Matrix-M™ adjuvant, which is designed to enhance the immune response and stimulate high levels of neutralizing antibodies.

Trial results were presented today at the World Vaccine Congress (WVC) Europe 2022. Previous initial trial results were presented at WVC in April 2022.

About the COVID-19-Influenza Combination Vaccine Candidate Phase 1/2 trial
The Phase 1/2 CIC vaccine trial evaluated a combination of Novavax' recombinant protein-based NVX-CoV2373, influenza vaccine candidate, and patented saponin-based Matrix-M adjuvant in a single formulation. The trial evaluated the safety, tolerability, and immune response to the CIC in 642 healthy adults aged 50 to 70. Participants were either previously infected with the SARS-CoV-2 virus that causes COVID-19 or vaccinated with an authorized vaccine at least eight weeks prior to enrollment. All participants were randomly assigned to cohorts to evaluate multiple formulations and were dosed on Day 0 and again at Day 56. The trial was conducted in Australia at 10 sites.

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 in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine 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 the vaccine 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. Food and Drug Administration, the European Commission, and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional populations and indications such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its CIC vaccine candidate in a Phase 1/2 clinical trial, 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, including NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, the CIC investigational vaccine candidate, its 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, controlling the pandemic and protecting populations, the efficacy, safety and intended utilization and administration of NVX-CoV2373 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; unanticipated challenges or delays in conducting clinical trials; 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 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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