Novavax Prototype COVID-19 Vaccine Data Support Homologous and Heterologous Boosting and Suggest Benefit Against Variants

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- *Homologous boosting with the prototype Novavax COVID-19 vaccine induced robust antibody titers for Omicron BA.1, BA.2, and BA.5*
- *Study 307 (Lot Consistency) achieved its primary endpoint, showing that three vaccine lots induced a comparable immune response thereby demonstrating the consistency of the manufacturing process*
- *A durable immunogenicity response was observed following primary vaccination as well as boosting which matched the levels previously associated with protection*

GAITHERSBURG, Md., Oct. 12, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today presented data from the Phase 3 PREVENT-19 trial and Study 307 (Lot Consistency) at the World Vaccine Congress Europe 2022. PREVENT-19 data in both adults aged 18 and older and adolescents aged 12 through 17 showed the prototype Novavax COVID-19 vaccine (NVX-CoV2373) achieved its pre-specified immunologic endpoint. Study 307 (Lot Consistency) met its primary endpoint, showing that three lots of the Novavax COVID-19 vaccine tested as a heterologous booster induced consistent immune responses in previously vaccinated adults aged 18 to 49.

"These data further demonstrate the consistent immunogenicity and safety profile of the Novavax COVID-19 vaccine as a booster, regardless of previous vaccine history," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "These data are an early indication that our vaccine may be effective against variants such as Omicron. We have ongoing trials further exploring the Novavax COVID-19 vaccine's potential as an effective booster against these variants, including BA.4/5, and look forward to sharing these data."

PREVENT-19 adult and adolescent homologous boosting

In the PREVENT-19 trial, a single homologous booster dose was given to select adult participants aged 18 and older, approximately eight or 11 months after their primary series. Following a booster dose, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) anti-spike (anti-S) Immunoglobulin G (IgG; a type of antibody) levels increased significantly relative to pre-boost levels, rising above the level correlated with 95% vaccine efficacy in a recent USG study. Neutralizing antibodies against the prototype strain also increased by 34- to 27-fold compared to pre-boost levels when boosted at eight or 11 months. Boosting also increased IgG and human angiotensin converting enzyme 2 (hACE2) receptor inhibition antibody levels against Omicron BA.1, BA.2, and BA.5 variants, with levels that are comparable to those observed in Phase 3 efficacy studies.

In the pediatric expansion of PREVENT-19 which evaluated boosting in adolescents aged 12 through 17, a single homologous booster dose was evaluated for anti-S IgG, hACE2 receptor inhibition and neutralization antibody responses. Following boosting, neutralizing titers were 2.7-fold higher than those seen with primary vaccination, and a significant boost was observed for antibody against Omicron BA.1, BA.2, and BA.5.

In both adults and adolescents, a third dose of the Novavax COVID-19 vaccine decreased the antigenic distance between SARS-CoV-2 variant and prototype virus strains, suggesting benefit for the prevention of COVID-19 against contemporary variants such as Omicron. Additionally, in both adults and adolescents, booster doses were well tolerated, with mostly mild to moderate reactogenicity that was of short duration.

Study 307 (Lot Consistency) adult homologous and heterologous boosting

Study 307 (Lot Consistency) achieved its primary endpoint, showing that three lots of the Novavax COVID-19 vaccine induced consistent immune responses in adults aged 18 to 49. Further, anti-S IgG titers were within the range previously found to correlate with high efficacy in the PREVENT-19 Phase 3 trial. Safety was also consistent across lots, with no serious related treatment-emergent adverse events (AE). These findings confirm a consistent vaccine manufacturing process.

Further, heterologous boosting responses were consistent across participants who received primary vaccines from Moderna, Pfizer, or Johnson & Johnson, with IgG levels approximating levels observed in PREVENT-19.

About PREVENT-19

PREVENT-19 (the PRE-fusion protein subunit Vaccine Efficacy Novavax Trial | COVID-19) is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 with Matrix-M adjuvant in 29,960 participants 18 years of age and over in 119 locations in the U.S. and Mexico. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least seven days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. In the trial, NVX-CoV2373 achieved 90.4% efficacy overall. It was generally well-tolerated and elicited a robust antibody response after the second dose in both studies. Full results of the trial were published in the *New England Journal of Medicine*.

The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the safety, effectiveness, and efficacy of NVX-CoV2373 with Matrix-M adjuvant in 2,247 adolescent participants 12 to 17 years of age in 73 locations in the U.S., compared with placebo. In the pediatric trial, the vaccine achieved its primary effectiveness endpoint (non-inferiority of the neutralizing antibody response compared to young adult participants 18 through 25 years of age from PREVENT-19) and demonstrated 80% efficacy overall at a time when the Delta variant of concern was the predominant circulating strain in the U.S. Additionally, immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied.

About Study 307 (Lot Consistency)

Study 307 (Lot Consistency) evaluated three different lots of the Novavax COVID-19 vaccine in approximately 900 adults aged 18 through 49, who received an initial primary series of the Novavax COVID-19 vaccine or other authorized or approved vaccines and a subset who had also received a booster shot with an authorized or approved COVID-19 vaccine at least six months prior. Participants were boosted with a single dose of the Novavax COVID-19 vaccine. Immunogenicity and safety were assessed, along with a comparison of IgG levels based on the vaccine that was used for the primary series. The study achieved its primary endpoint, showing that three lots of the Novavax COVID-19 vaccine tested induced consistent immune responses. Further, anti-S IgG titers were within the range previously found to correlate with high efficacy in the PREVENT-19 Phase 3 trial. Safety was also consistent across lots, with no serious related treatment-emergent AEs. These findings confirm a consistent vaccine manufacturing process.

About the Novavax COVID-19 vaccine (NVX-CoV2373)

The Novavax COVID-19 vaccine (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 (S) protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. The Novavax COVID-19 vaccine 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 World Health Organization. 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 COVID-19-Influenza Combination 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, a COVID-seasonal influenza combination 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, intended utilization, and expected 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.

Contacts:
Investors
Erika Schultz | 240-268-2022
ir@novavax.com

Media
Ali Chartan or Giovanna Chandler | 202-709-5563
media@novavax.com

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