Novavax Announces Initial Omicron Cross-Reactivity Data from COVID-19 Vaccine Booster and Adolescent Studies

December 22, 2021

- Two-dose primary regimen of NVX-CoV2373 demonstrated cross-reactive immune responses against Omicron (B.1.1.529) and other variants

- Third dose produced increased immune responses comparable to or exceeding levels associated with protection in Phase 3 clinical trials, with a 9.3-fold IgG rise and a 19.9-fold ACE2 inhibition increase after booster dose

- Immune responses in adolescents were 2- to 4-fold higher than adults against broad array of variants of interest and variants of concern

- Development of Omicron-specific vaccine on track for initiation of GMP manufacturing in early January

- Company to host investor conference call today from 4:30 - 5:00 pm ET

GAITHERSBURG, Md., Dec. 22, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced initial data evaluating the immune response of its COVID-19 vaccine, NVX-CoV2373, against the Omicron variant as well as additional data from its ongoing Phase 2 boost study. New results demonstrate broad cross-reactivity against Omicron and other circulating variants from a primary 2-dose regimen, with responses that increased following a third dose at six months.

Immune responses included the following:

- Anti-spike IgG titers after Dose 3 increased 5.4-fold (prototype) to 9.3-fold (Omicron) from peak responses seen after 2-dose primary vaccination.
    - This represents a 61.1-fold (prototype) and a 73.5-fold (Omicron) increase from prior to the Dose 3 boost.
- ACE2-inhibition titers increased 6-fold (prototype) to 19.9-fold (Omicron) compared to peak responses following 2-dose primary series, representing a 54.4-fold (prototype), a 24.4-fold (Delta) and a 36.3-fold (Omicron) increase from prior to the booster.
- Wild-type neutralization responses were observed after 2 doses for prototype, Delta and Omicron. Significant increases were observed after boosting, with titers for Delta and Omicron comparable to levels associated with protection in U.S. and Mexico and U.K. Phase 3 studies.
    - After 2 doses, Omicron wild-type neutralization was <4-fold lower than prototype, suggesting that both a booster dose as well as an Omicron-specific vaccine may be beneficial.

Further, data from the pediatric expansion of Novavax' PREVENT-19 Phase 3 trial in the U.S. and Mexico showed robust immune responses in adolescents, including increased IgG and receptor inhibition titers against a wide array of variants, including Omicron, following a 2-dose series. Responses in adolescents were 2- to 4-fold higher than adults against all evaluated variants.

"In the midst of an evolving pandemic, NVX-CoV2373 showed strong immune responses against Omicron and other circulating variants. We are encouraged that boosted responses against all variants were comparable to those associated with high vaccine efficacy in our Phase 3 clinical trials, suggesting that NVX-CoV2373 can play an important role in the ongoing fight against new variants," said Gregory M. Glenn, President of Research and Development, Novavax. "Given the continued evolution of the coronavirus, the development of an Omicron vaccine could be necessary. Novavax has cloned, expressed and characterized the Omicron spike protein vaccine and will soon enter the GMP-phase of production. We expect to begin clinical studies in the first quarter of 2022."

As part of an ongoing study, a single booster dose of 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant was administered to healthy adult participants approximately six months after their primary 2-dose vaccination series. Multiple assays were used to evaluate immune responses against SARS-CoV-2 twenty-eight days following the booster dose.

Safety reporting of reactogenicity events showed an increasing trend across all 3 doses of NVX-CoV2373, reflecting the increased immunogenicity seen with a third dose. Following the booster, local and systemic reactions were generally short-lived with a median duration of approximately 2 days. The incidence of Grade 3 or higher events remained relatively low. Medically attended adverse events (MAAEs), potentially immune-mediated medical conditions (PIMMCs), and severe adverse events (SAEs) occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.

The major findings, detailed in '*Immunogenicity and Safety Following a Homologous Booster Dose of a SARS-CoV-2 recombinant spike protein vaccine (NVX-CoV2373): A Phase 2 Randomized Placebo-Controlled Trial*,' will be submitted for peer-review publication and are expected to be available online at https://www.medrxiv.org/ in the coming days.

Conference Call
Novavax will host a conference call for investors today at 4:30 p.m. ET. The dial-in numbers for the conference call are (877) 870-4263 (Domestic) or (412) 317-0790 (International). Participants will be prompted to request to join the Novavax, Inc. call. A replay of the conference call will be available starting at 7:30 p.m. ET on December 22, 2021 until 11:59 p.m. ET on December 31, 2021. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 6207101.

A webcast of the conference call can also be accessed on the Novavax website at novavax.com/events. A replay of the webcast will be available on the Novavax website until March 22, 2022.

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. NVX-CoV2373 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. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

Novavax' COVID-19 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. The current assigned shelf life of the vaccine is 9 months.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

About the NVX-CoV2373 Phase 3 trials
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

A trial conducted in the U.K. with 14,039 participants was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline. Full results of the trial were published in the *New England Journal of Medicine* *(NEJM)*.

PREVENT-19, a trial in the U.S. and Mexico, with 25,452 participants, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 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%. The key secondary endpoint is 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. It was generally well-tolerated and elicited a robust antibody response in both studies. Full results of the trial were published in *NEJM*.

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. NVX-CoV2373, the company's COVID-19 vaccine, received Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, Emergency Use Authorization in Indonesia and the Philippines, and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. 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 Twitter, LinkedIn, Instagram and Facebook.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to submit a complete CMC data package to the U.S. FDA by the end of the year, and the efficacy, safety and intended utilization 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 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 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, 2020 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
Novavax, Inc.
Erika Schultz | 240-268-2022
ir@novavax.com

Solebury Trout
Alexandra Roy | 617-221-9197
aroy@soleburytrout.com

Media
Ali Chartan | 240-720-7804
Laura Keenan Lindsey | 202-709-7521
media@novavax.com

SOURCE Novavax, Inc.