Novavax Announces COVID-19 Vaccine Booster Data Demonstrating Four-Fold Increase in Neutralizing Antibody Levels Versus Peak Responses After Primary Vaccination

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- *Single booster dose at 6 months of NVX-CoV2373 increased wild-type neutralizing antibodies more than 4-fold versus primary vaccination series*
- *Six-fold increase in cross-reactive functional antibodies to Delta variant compared to primary vaccination series*
- *Analysis of sera from primary vaccination series also showed cross-reactive functional antibodies to Alpha, Beta and Delta variants, all of which increased 6- to 10-fold with boost*
- *Study reinforces mostly mild and transient side effect profile*

GAITHERSBURG, Md., Aug. 5, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced preliminary data demonstrating that a single booster dose of its recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, NVX-CoV2373, given six months after an initial two-dose regimen, elicited a 4.6-fold increase in functional antibody titers. Additionally, functional ACE-2 binding inhibition antibodies cross-reactive with the Delta (B.1.617.2) variant were more than 6-fold higher than the primary vaccination series. Complete data from the study will be submitted to a peer review publication and posted to a preprint server.

The results come from an ongoing Phase 2 study in the U.S. and Australia in which select participants in the 5-microgram dose cohort received a 5-microgram booster dose 189 days after the initial two-dose regimen to examine the functional immune response.

"The strong results from this study reinforce our confidence in the potential for a booster dose of NVX-CoV2373 to provide broad protection against disease, including from known and emerging variants," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "Given the evidence that natural and vaccine-induced immunity wanes over time, the continuation of our proactive clinical development program will be critical to understanding and demonstrating the effectiveness of our recombinant nanoparticle COVID-19 vaccine."

Twenty-eight days following boosting, anti-spike IgG increased approximately 4.6-fold compared to the peak response seen after the second dose (Day 217 GMEU = 200,408 (95% CI: 159,796; 251,342)). This boosted value represents a 3.7 to 4.4-fold increase in anti-spike IgG values that were associated with protection in Novavax' PREVENT-19 and U.K. Phase 3 clinical studies.

Similarly, wild-type neutralization responses increased approximately 4.3-fold compared to the peak response seen after Dose 2 (IC50 neutralization titers = 6,231 (95% CI: 4,738; 8,195)). This boosted value represents a 4.6 to 5.5-fold increase over the neutralization response associated with protection in the PREVENT-19 and U.K. Phase 3 clinical trials. Older participants (aged 60-84) showed a 5.4-fold increase in antibody responses, while younger participants (aged 18-59) showed a 3.7-fold increase. Very high levels of functional antibodies to the Alpha (B.1.1.7), Beta (B.1.351) and Delta variants were induced by boosting with NVX-CoV2373, with a 6.6-fold higher Delta variant-specific response when compared to the Delta response observed with the primary vaccination series.

The administration of the booster dose was generally well-tolerated. Local and systemic reactogenicity increased between Dose 1, Dose 2 and Dose 3, with 90% of symptoms rated as mild or moderate after the third dose.

In addition to the ongoing Phase 1/2 boost study, NVX-CoV2373 is one of seven COVID-19 vaccines being evaluated as part of COV-Boost, a "mix-and-match" study being conducted by the University Hospital Southampton NHS Foundation Trust and other U.K. National Institute for Health Research sites and supported by the U.K. Vaccines Task Force and Department of Health and Social Care. COV-Boost is evaluating heterologous boosting in individuals who previously received two doses of an authorized vaccine. NVX-CoV2372 is also being evaluated in Com-COV2, which is exploring heterologous regimen of COVID-19 vaccines from different manufacturers.

About NVX-CoV2373
NVX-CoV2373 is a protein-based vaccine candidate 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. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall; and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults and will be advanced for regulatory submission. Both 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 and LinkedIn.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-CoV2373 and other Novavax vaccine product candidates, and the potential for a booster dose of NVX-CoV2373 to provide broad protection against COVID-19 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; 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.

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