Novavax Phase 3 COVID-19 Omicron Trial Supports the Continued and Future Use of Novavax Prototype Vaccine as a Booster

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- *The Novavax BA.1 vaccine candidate met its primary strain-change endpoint allowing for development of variant vaccines, if necessary*
- *Novavax' prototype vaccine induced broad immune response against original Wuhan, BA.1, and BA.5 strains*
- *The trial showed no benefit for a bivalent vaccine utilizing Novavax' recombinant protein/adjuvant technology*

GAITHERSBURG, Md., Nov. 8, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced topline results from its Phase 3 Boosting Trial for the SARS-CoV-2 rS Variant Vaccines (COVID-19) showing that the Company's BA.1 vaccine candidate (NVX-CoV2515) met the primary strain-change endpoint. The data demonstrate that the BA.1 vaccine candidate neutralizing responses in those not previously exposed to COVID-19 were greater than those of the prototype vaccine (NVX-CoV2373), enabling a shift to a new variant vaccine, if necessary (see chart 1).

Additionally, data show no benefit for the Novavax bivalent vaccine candidate compared to the BA.1 vaccine candidate or prototype vaccine in the overall trial population. Immunoglobulin G (IgG) antibody responses against BA.1 and prototype strains showed similar responses across the three vaccine groups (prototype [n=273], BA.1 vaccine candidate [n=279], and bivalent – prototype + BA.1 vaccine candidate [n=277]).* Importantly, for the BA.5 strain (which is structurally similar to BA.1), pseudoneutralization responses demonstrated that there was no benefit for the BA.1 or bivalent vaccine candidates compared to the prototype vaccine.**

Overall, the data demonstrated that the prototype vaccine induced a broad immune response against original prototype, BA.1, and BA.5 strains. The prototype vaccine induced robust IgG responses to both BA.1 and the matched prototype strain.* Pseudoneutralization responses against BA.5 for the prototype vaccine were comparable to those induced by the more closely matched BA.1 vaccine and bivalent vaccine candidates.*

"Today's results show that use of our prototype vaccine as a booster induces cross-reactive responses to a broad range of variants with the potential to protect against future strains. This is a hallmark of our vaccine technology and shows the suitability of our current prototype vaccine as a booster even as the COVID-19 landscape continues to evolve," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "Our vaccine, which provides broad immune response even in the face of evolving variants, presents a potential strategy to protect against COVID-19 now and into the future."

When given as a second booster dose (fourth dose), all three vaccine formulations were similarly well-tolerated, consistent with the well-established safety profile of the prototype vaccine. The most common local solicited symptom was pain/tenderness (BA.1 69%, prototype 71%, bivalent 65%). The most common systemic solicited symptoms were fatigue and malaise (BA.1 45%, prototype 41%, bivalent 45%), headache (BA.1 38%, prototype 35%, bivalent 36%), muscle pain (BA.1 25%, prototype 24%, bivalent 24%), and joint pain (BA.1 10%, prototype 11%, bivalent 6%), with the majority of reactions being mild or moderate.

Chart 1: Geometric Mean Ratio of BA.1 wild-type Neutralizing Responses (Day 14) Study Arm in Participants Not Previously Infected

	Group Comparisons		
Neutralizing antibodies for BA.1	BA.1 vaccine to prototype vaccine	Bivalent vaccine to prototype vaccine	Bivalent vaccine to BA.1 vaccine
Geometric Mean Ratio (GMR)	1.6	1.2	0.7
GMR 95% Confidence Interval	1.31, 2.03	0.94, 1.44	0.57, 0.89

*IgG responses are not statistically significant.
**Fit-for-purpose analysis being confirmed with validated assay.

About the Phase 3 Omicron Trial
Novavax' Phase 3 Omicron trial is a two-part, observer blinded, randomized trial to evaluate Omicron subvariant vaccine

candidates. NVX-CoV2515 (BA.1) and bivalent (NVX-CoV2373 + Omicron subvariant NVX-CoV2515) vaccine candidates were compared to NVX-CoV2373 in adults aged 18 to 64 previously vaccinated with three doses of mRNA vaccines. All formulations include the Matrix-M™ adjuvant to enhance and broaden the immune response. The trial is evaluating the reactogenicity and immune responses to all three formulations. The trial's primary endpoints include measures of immune response, and its secondary endpoints include additional measurements of immune responses and safety measures. The trial plans to enroll 2,090 adults aged 18 to 64 across 19 sites in Australia.

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 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 (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, 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, 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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