Novavax Announces Positive Results from First Study of Influenza Vaccine and COVID-19 Vaccine Candidate Administered Simultaneously

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GAITHERSBURG, Md., June 14, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced data from the first co-administration study of a SARS-CoV-2 vaccine candidate [Novavax, NVX-CoV2373] and an approved influenza vaccine [Seqirus, adjuvanted, trivalent seasonal influenza vaccine (aTIV) or a cell-based, quadrivalent seasonal influenza vaccine (QIVc)]. The findings suggest simultaneous vaccination may be a viable immunization strategy. In addition, the protection afforded by the candidate vaccine was consistent with the main study at 87.5% and 89.8% respectively. A preprint of the manuscript, '*Safety, Immunogenicity, and Efficacy of a COVID-19 Vaccine (NVX-CoV2373) Co-administered With Seasonal Influenza Vaccines*,' is available at medRxiv.org and has been submitted for peer-review.

As part of Novavax' Phase 3 clinical trial of NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine candidate, in the United Kingdom, 431 volunteers were also enrolled in a co-administration sub-study, led by researchers at St George's, University of London and St George's Hospital, London. All received an approved seasonal influenza vaccine with approximately half the participants co-vaccinated with NVX-CoV2373 while the remainder received placebo. The study demonstrated that vaccine efficacy appeared to be preserved in those receiving both vaccines compared to those vaccinated with NVX-CoV2373 alone.

"As the next influenza season approaches and people still need a primary COVID-19 vaccine series or a booster, separate healthcare visits to cover both COVID-19 and influenza vaccinations will be burdensome," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "As the first clinical study to evaluate safety, immunogenicity, and efficacy of a COVID-19 vaccine when co-administered with a seasonal influenza vaccine, these results demonstrate the promising opportunity for concomitant vaccination, which may improve the uptake of both vaccines."

A Favorable Safety and Reactogenicity Profile and Robust Immune Response

Local and systemic reactogenicity was largely absent or mild in all groups with only a few events such as pain and tenderness at the injection site and muscle aches being elevated in those co-vaccinated. Local events generally lasted 1-2 days, while systemic events lasted approximately one day for both the co-vaccinated group and the group that received only NVX-CoV2373. In addition to reactogenicity, participants were monitoring for unsolicited adverse events (AEs), medically attended AEs (MAAEs), and serious AEs (SAEs).

Rates of severe events were low in all groups and there were no additional early safety concerns associated with co-administration. Rates of unsolicited AEs, MAAEs, and SAEs were low and balanced between the groups.

"This study shows how important it is to assess the safety profile and immune responses when COVID-19 and influenza vaccines are administered at the same time," said Professor Paul Heath, FRCPCH, Vaccine Institute, St George's, University of London and St George's Hospital, London, who is chief investigator of the Novavax United Kingdom trial. "The results are reassuring and we are excited by the possibility of concomitant use of these vaccines as an important tool in the fight against both of these important respiratory viruses."

Furthermore, immunogenicity of the influenza vaccine was preserved with concomitant administration while a modest decrease in the immunogenicity of the NVX-CoV2373 vaccine was found. Vaccine efficacy in the sub-study was 87.5% (95% CI: -0.2, 98.4) while efficacy in the main study was 89.8% (95% CI: 79.7, 95.5) against SARS-CoV-2. Despite the decrease in the immunogenicity with concomitant vaccination, anti-Spike antibody levels were more than 3-fold higher than levels found in convalescent serum in those who received both vaccines.

"These data could be used to help inform guidance or recommendations on the co-administration of influenza and COVID-19 vaccines, overcoming challenges and contributing towards a new normal to protect at-risk populations from both infections," said Raja Rajaram, M.D., Medical Affairs Lead, EMEA, Seqirus, a co-author of the study. "Seqirus is committed to advancing the science underpinning influenza and taking our place on the front line, alongside our public health partners,

as a reliable influenza vaccine supplier."

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 adjuvanted with Novavax' patented saponin-based Matrix-M™ 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 B.1.1.7/501Y.V1 variant and 89.7% 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 and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2020, 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 sec.gov, 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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