Novavax Announces Positive Preclinical Data for Combination Influenza and COVID-19 Vaccine Candidate

- Manuscript highlights development of robust responses to both influenza and COVID-19 and protection against the SARS-CoV-2 virus

- Data shared via preprint server for biology, bioRxiv, ahead of publication

GAITHERSBURG, Md., May 10, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced data from a preclinical study of the company's combination quadrivalent seasonal flu vaccine (NanoFlu™) and COVID-19 vaccine candidate (NVX-CoV2373). The NanoFlu/NVX-CoV2373 combination vaccine demonstrated positive immune responses to both influenza and SARS-CoV-2. A pre-print of the manuscript is available at bioRxiv.org.

The manuscript, titled 'Combination Respiratory Vaccine Containing Recombinant SARS-CoV-2 Spike and Quadrivalent Seasonal Influenza Hemagglutinin Nanoparticles with Matrix-M™ Adjuvant,' studied a combination vaccine comprising a quadrivalent nanoparticle influenza vaccine formulated together with a recombinant SARS-CoV-2 spike protein vaccine and Matrix-M™ adjuvant. The combination vaccine elicited robust responses to both influenza A and B and protected against the SARS-CoV-2 virus. Clinical studies of the combination vaccine are expected to begin by the end of the year.

"Despite low rates during the COVID-19 pandemic, influenza remains a significant risk to global public health and the need for versatile, more effective vaccines is as important as ever, including against the flu. This study's results build on our success to-date with NVX-CoV2373, and with NanoFlu, which successfully achieved all of its objectives in a pivotal Phase 3 trial announced last year," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "We believe that this novel combination vaccine candidate, which leverages Novavax' technology platform and Matrix-M™ adjuvant, could be an important future tool in the long-term fight against both of these harmful respiratory viruses."

Immunogenicity Results

The preclinical study found that the combination NanoFlu/NVX-CoV2373 (qNIV/CoV2373) vaccine induced functional influenza and COVID antibodies in ferrets. Hemagglutination inhibition (HAI) and ACE2 receptor-inhibiting titers were comparable between immunization with the combination vaccine and with its respective component vaccines. Antibody titers were elevated two weeks after a single dose and increased even further two weeks following a second immunization.

Hamsters that received the combination NanoFlu/NVX-CoV2373 vaccine had elevated levels of SARS-CoV-2 anti-S IgG two weeks after the first immunization, which increased significantly after a second dose, with levels comparable to animals that received the NVX-CoV2373 vaccine alone. Human ACE2 receptor inhibiting antibody levels responded similarly. The immune responses to influenza A and B strains elicited by NanoFlu/NVX-CoV2373 were comparable to immunization with NanoFlu alone. Further, the combination vaccine induced antibodies against SARS-CoV-2 neutralizing epitopes, including at hidden or cryptic sites, that are common between USA-WA1 and the B.1.351 variant.

Protection after SARS-CoV-2 challenge

When hamsters were challenged with SARS-CoV-2, animals immunized with NanoFlu/NVX-CoV2373 retained their body weight comparably to non-infected animals and those immunized with NVX-CoV2373 alone. An examination of viral load in the upper and lower respiratory tract showed that little or no virus was detected four days after COVID-19 infection in animals immunized with NanoFlu/NVX-CoV2373 or with just NVX-CoV2373. Microscopic and macroscopic observations of the lungs showed no remarkable findings in animals immunized with either the combination vaccine or with NVX-CoV2373 alone.

"Seasonal influenza and COVID-19 combination vaccines will likely be critical to combating emerging COVID-19 variants," said Russell 'Rip' Wilson, Executive Vice President and NanoFlu General Manager, Novavax. "Millions of people are affected by influenza each year in the U.S., and despite our vaccination efforts, currently available

flu vaccines are only partially effective. Our NanoFlu vaccine Phase 3 clinical trial achieved all of its primary endpoints, and we expect this combination vaccine will help control both COVID-19 and influenza illness."

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 100% protection against severe disease, 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 began in December 2020. 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 100% protection against severe disease 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™
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 NanoFlu™
NanoFlu™ is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M™ adjuvant.

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.

Novavax 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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