Novavax to Participate in University of Oxford Com-COV3 Study Comparing Mixed COVID-19 Vaccine Schedule in Adolescents

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GAITHERSBURG, Md., Sept. 16, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced its participation in a newly expanded Phase 2 clinical trial called *Comparing COVID-19 Vaccine Schedule Combinations – Stage 3* (Com-COV3), led by the University of Oxford and funded by the UK Vaccines Taskforce (VTF) and the National Institute for Health Research (NIHR). Novavax' recombinant nanoparticle COVID-19 vaccine candidate, NVX-CoV2373, is one of the three COVID-19 vaccines that will be studied in adolescents to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19.

"Expanding our understanding of how different COVID-19 vaccines can be used to implement flexible vaccine programs across all age groups will be vital to ultimately controlling the pandemic," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "A mixed vaccination series could offer the potential to maximize the use of existing vaccine supply, increase the total number of individuals who can ultimately be vaccinated and accelerate rapid and equitable access across the globe."

Com-COV3 will include at least 360 adolescents 12-16 years of age. Volunteers will receive an authorized vaccine as a first dose and then at least 8 weeks later will receive one of three different vaccines as a second dose. All participants will be randomly allocated at the time of the second dose to receive either a full dose or half dose of the same vaccine given for the first dose, a full dose of the Novavax vaccine or a half dose of a different authorized vaccine. The research will compare the immune system responses from those who receive a heterologous regimen to those who receive a homologous regimen.

Under the protocol, participants will be followed for reactogenicity (safety) and immune responses. Results from the study are expected within a few months. The UK Medicines and Healthcare products Regulatory Agency (MHRA) and Joint Committee on Vaccination and Immunisation (JCVI) will formally assess the safety and efficacy of any new vaccination process before advising whether it is rolled out.

Novavax is also participating in University of Oxford's Com-COV2 study, in which NVX-CoV2373 is one of four COVID-19 vaccines being studied to evaluate the potential for combined regimens that mix vaccines from different manufacturers to achieve immune protection against COVID-19. Results from Com-COV2 are expected in the coming weeks. Additional information is available via the study website www.comcovstudy.org.uk.

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 its partnerships, and other Novavax vaccine product candidates, Novavax' participation in Com-COV3, the study protocol, the timing of study results and potential benefits of the study, timing of future regulatory actions, and the role that Novavax may play in helping control the COVID-19 pandemic 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.

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