Novavax Announces Positive Results of COVID-19 Vaccine in Pediatric Population of PREVENT-19 Phase 3 Clinical Trial

February 10, 2022

- PREVENT-19 pediatric expansion in adolescents aged 12 through 17 achieved primary effectiveness endpoint demonstrating comparability to adult population

- Trial demonstrated 82% clinical efficacy against Delta variant

- Immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied

- Vaccine was well-tolerated with no safety signals identified

- Novavax plans to supplement global regulatory filings with pediatric data in Q1 2022

- Company to host investor conference call today from 4:30 - 5:00 pm ET

GAITHERSBURG, Md., Feb. 10, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine, achieved its primary effectiveness endpoint in the pediatric expansion of its PREVENT-19 pivotal Phase 3 trial and demonstrated 80% efficacy overall at a time when the Delta variant was the predominant circulating strain in the U.S. The study enrolled 2,247 adolescents aged 12 through 17-years across 73 sites in the U.S. to evaluate safety, effectiveness (immunogenicity), and efficacy, with an emphasis on ensuring well balanced racial and ethnic representation among participants.

"We are encouraged by the results in this adolescent population given the ongoing need for alternative vaccine options for COVID-19," said Filip Dubovsky, MD, Chief Medical Officer, Novavax. "We believe the Novavax vaccine offers a differentiated technology and option for this younger population given its established protein-based technology already used in other vaccines, and the positive responses demonstrated against variants."

The primary PREVENT-19 pivotal Phase 3 trial conducted in adults aged 18 years and older, results of which were published in *The New England Journal of Medicine (NEJM)*, enrolled approximately 30,000 participants in the U.S. and Mexico. NVX-CoV2373 achieved 90.4% efficacy overall and demonstrated a reassuring safety and tolerability profile. Serious and severe adverse events in adults were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed in adults during clinical studies (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. Novavax will continue to collect and analyze real-world data, for both the primary PREVENT-19 trial and the pediatric expansion, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

NVX-CoV2373 has not yet been authorized in the adolescent population. Novavax expects to submit its regulatory filings for a pediatric indication in adolescents aged 12 through 17-years to global regulatory authorities during the first quarter of 2022. Novavax also expects to initiate additional studies globally evaluating younger age groups during the second quarter of 2022.

To date, NVX-CoV2373 has received authorization from multiple regulatory authorities globally, including conditional marketing authorization from the European Commission, the Medicines and Healthcare products Regulatory Agency, and emergency use listing (EUL) from the World Health Organization (WHO). With WHO EUL, there is the opportunity for authorization in over 170 countries with a potential reach of over six billion lives. The vaccine is also currently under review by multiple regulatory agencies worldwide, including the U.S. Food and Drug Administration (FDA).

Results:Clinical efficacy consistent between adolescent and adult participants

In the placebo-controlled, observer-blinded study, adolescent participants were randomized 2:1 to receive active vaccine or placebo. Study participants underwent blinded crossover to alternate study material after the required safety data were collected to ensure that all participants received active vaccine. During the period of placebo-controlled observation, NVX-CoV2373 demonstrated overall protective efficacy of 79.5% (95% CI: 46.8, 92.1) against COVID-19. Efficacy was

consistent across age groups and all cases observed in the vaccine group were mild as defined by the trial protocol.

Efficacy endpoints were accrued from May 24 through September 27, 2021 – a time when the Delta variant was the predominant strain in the U.S., showing high transmission and high severity of disease. Sequence data are available for 11 of the 20 confirmed cases, 100% of which were determined to be caused by the Delta variant. Vaccine efficacy against the Delta variant was 82.0% (95% CI: 32.4, 95.2).

Results: Consistent response to variants

Data from the pediatric expansion of PREVENT-19 showed in post hoc analyses robust immune responses in adolescents, including IgG responses against Spike proteins of several variants (including Alpha, Beta, Delta, Gamma, Mu, and Omicron) that were 2-3-fold higher than in adults, with 100% seroconversion against all variants following a 2-dose series of vaccinations. Adolescent functional immune responses (hACE2 receptor inhibition) against these variants were 2.4-4-fold higher than in adults against all evaluated variants.

Results: A reassuring safety and reactogenicity profile

Preliminary safety data from the pediatric expansion of PREVENT-19 showed the vaccine to be generally well-tolerated. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups, and not considered related to the vaccine. Local and systemic reactogenicity was generally lower than or similar to adults, after the first and second dose. The most common adverse reactions observed were injection site tenderness/pain, headache, myalgia, fatigue, and malaise. There was no increase in reactogenicity in younger (12 to <15 years old) adolescents compared to older (15 to <18 years old) adolescents. No safety signal was observed through the placebo-controlled portion of the study.

Study Endpoints

The pediatric expansion of PREVENT-19 achieved its primary effectiveness (immunogenicity) endpoint, with neutralizing antibody responses non-inferior to those observed in young-adult (18 to 26 years old) participants from PREVENT-19. Adolescent neutralizing antibody responses using wild-type SARS-CoV-2 were approximately 1.5-fold higher in adolescents than in young adults, meeting FDA-specified criteria.

About PREVENT-19
PREVENT-19 (the **PRE**-fusion protein subunit **V**accine **E**fficacy **N**ovavax **T**rial | COVID-**19**) is a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M™ adjuvant in 29,960 participants 18 years of age and older in 119 locations in the United States and Mexico, compared with placebo. The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the safety, effectiveness, and efficacy of NVX-CoV2373 with Matrix-M™ adjuvant in 2,247 adolescent participants 12- to 17-years of age in 73 locations in the United States, compared with placebo.

PREVENT-19 is being conducted with support from the U.S. government, including the Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS. BARDA is providing up to $1.75 billion under a Department of Defense agreement.

Conference Call
Novavax will host a conference call for investors today at 4:30 p.m. ET. The dial-in numbers for the conference call are (877) 870-4263 (Domestic) or (412) 317-0790 (International). Participants will be prompted to request to join the Novavax, Inc. call. A replay of the conference call will be available starting at 7:30 p.m. ET on February 10, 2022 until 11:59 p.m. ET on February 17, 2022. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 3932770.

A webcast of the conference call can also be accessed on the Novavax website at novavax.com/events. A replay of the webcast will be available on the Novavax website until May 10, 2022.

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. 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.

Novavax' COVID-19 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 NVX-CoV2373 worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India (SII), 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 the NVX-CoV2373 Phase 3 trials
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

PREVENT-19, a trial in the U.S. and Mexico that enrolled almost 30,000 participants aged 18 years and older, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. It was generally well-tolerated and elicited a robust antibody response after the second dose in both studies. Full results of the trial were published in the *New England Journal of Medicine (NEJM).*

A trial conducted in the U.K. with 14,039 participants aged 18 years and older was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline. Full results of the trial were published in*NEJM*.

About Matrix-M™ Adjuvant
Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and generally 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. NVX-CoV2373, the company's COVID-19 vaccine, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is also under review by multiple regulatory agencies worldwide. In addition to its COVID-19 vaccine, Novavax is also currently evaluating a COVID-seasonal influenza combination vaccine in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu, its quadrivalent influenza investigational vaccine candidate. 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 Twitter, LinkedIn, Instagram and Facebook.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, including Novavax' plans to initiate additional global studies in Q1 2022, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement global regulatory filings with the pediatric data in Q1 2022 and the opportunity for authorization in over 170 countries, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and the efficacy, safety and intended utilization 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 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.

Contacts:

Investors
Novavax, Inc.
Erika Schultz | 240-268-2022
ir@novavax.com

Solebury Trout
Alexandra Roy | 617-221-9197
aroy@soleburytrout.com

Media
Ali Chartan | 240-720-7804
Laura Keenan Lindsey | 202-709-7521
media@novavax.com

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