# World Health Organization Grants Second Emergency Use Listing for Novavax COVID-19 Vaccine

December 20, 2021

*- Nuvaxovid™ COVID-19 Vaccine (SARS-CoV-2 rS [Recombinant, adjuvanted]) listed for emergency use by the WHO*

*- EUL for Nuvaxovid complements listing for Novavax vaccine manufactured and marketed by Serum Institute of India as Covovax™*

*- EUL by WHO is a prerequisite for exports to numerous countries participating in the COVAX Facility*

GAITHERSBURG, Md., Dec. 20, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that the World Health Organization (WHO) has granted a second Emergency Use Listing (EUL) for NVX-CoV2373, Novavax' recombinant protein nanoparticle COVID-19 vaccine with Matrix-M™ adjuvant, for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. Today's EUL pertains to vaccine to be marketed by Novavax as Nuvaxovid™ COVID-19 Vaccine (SARS-CoV-2 rS [Recombinant, adjuvanted]) in Europe and other markets. NVX-CoV2373 is also being manufactured and marketed in India and licensed territories by Serum Institute of India Pvt. Ltd. (SII), as Covovax™, which was granted EUL on December 17. Nuvaxovid and Covovax are based on the same Novavax recombinant protein technology and the EULs are based on a common pre-clinical, clinical and chemistry, manufacturing and controls (CMC) package.

Today's EUL follows the receipt of conditional marketing authorization from the European Commission and prequalifies Nuvaxovid as meeting WHO standards for quality, safety and efficacy. EUL is a prerequisite for exports to numerous countries, including those participating in the COVAX Facility, which was established to enable equitable vaccine allocation and distribution. EUL also allows countries to expedite their own regulatory approval to import and administer COVID-19 vaccines. Novavax and SII have committed a cumulative 1.1 billion doses of the Novavax vaccine to COVAX.

"Today's Emergency Use Listing underscores the ongoing need and potential for Novavax to help significantly increase COVID-19 vaccine access across the globe through a protein-based option built on a well-understood platform," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the World Health Organization for its thorough assessment and look forward to helping address major obstacles to controlling the pandemic, including practical barriers to access and vaccine hesitancy."

"We welcome the news that Nuvaxovid has also received WHO Emergency Use Listing, providing the world – and COVAX participants – with another promising class of vaccine as well as yet another tool in the battle against COVID-19," said Dr. Seth Berkley, CEO of Gavi, the Vaccine Alliance. "With data on safety and efficacy against several variants, strong potential in booster regimens, and standard storage temperatures, Nuvaxovid will provide countries with another critical option in the quest to help protect their populations."

"It is very welcome news that the world now has an additional weapon from Novavax in its arsenal of tools to fight COVID-19," said Dr Richard Hatchett, Chief Executive Officer, Coalition for Epidemic Preparedness Innovations (CEPI). "CEPI's investments to accelerate the clinical development and manufacturing of Novavax' vaccine have been critical to progressing this vaccine and enabling equitable access through COVAX."

The grant of EUL was based on the totality of preclinical, manufacturing and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants in the U.S. and Mexico, the results of which were published in the*New England Journal of Medicine* *(NEJM)*; and a trial that evaluated the vaccine in more than 14,000 participants in the U.K., the results of which were also published in *NEJM*. In both trials, NVX-CoV2373 demonstrated high efficacy and a reassuring safety and tolerability profile. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

Novavax' COVID-19 vaccine was recently granted emergency use authorization (EUA) in Indonesia and the Philippines, where it will be marketed as Covovax by SII. NVX-CoV2373 is also currently under review by multiple regulatory agencies worldwide. The company expects to submit its complete CMC data package to the U.S. FDA by the end of the year. The brand name Nuvaxovid™ has not yet been authorized for use in the U.S. by the FDA.

For more information on Nuvaxovid and Covovax or to request additional information please visit the following websites:

- Novavax global authorization website
- World Health Organization

**Emergency Use Listing of Nuvaxovid™ by the World Health Organization**
The World Health Organization (WHO) has issued Emergency Use Listing for Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

**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.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

**About the NVX-CoV2373 Phase 3 trials**
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

A trial conducted in the U.K. with 14,039 participants 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.

PREVENT-19, a trial in the U.S. and Mexico, with 25,452 participants, 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%. The key secondary endpoint is 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 in both studies.

**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. NVX-CoV2373, the company's COVID-19 vaccine, received Emergency Use Authorization in Indonesia and the Philippines and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. 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, the scope, timing and outcome of future regulatory filings and actions, including Novavax'

plans to submit a complete CMC data package to the U.S. FDA by the end of the year, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations 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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