

GAITHERSBURG, Md., Feb. 14, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced its submission to Swissmedic, the Swiss Agency for Therapeutic Products, for conditional marketing authorization (CMA) of NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant, for use in adults.

"We remain committed to delivering our COVID-19 vaccine, built on a well-understood protein platform used in common vaccines for decades," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We look forward to Swissmedic's review and, if authorized, delivering the vaccine to Switzerland to help fill the continued gap in vaccination and global distribution channels."

The submission for the regulatory evaluation by Swissmedic of NVX-CoV2373 includes data from two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants aged 18 years and older in the U.S. and Mexico and was published in the *New England Journal of Medicine (NEJM)*; and a trial with almost 15,000 adult participants in the U.K. which was also published in *NEJM*. In both trials, the vaccine demonstrated efficacy with a reassuring safety profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed during clinical studies (frequency category of very common $\geq 1/10$) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

NVX-CoV2373 has been granted conditional authorization by multiple regulatory agencies worldwide, including the [European Commission](#), the [Medicines and Healthcare products Regulatory Agency](#), and emergency use listing from the [World Health Organization](#). The vaccine is also currently under review by multiple regulatory agencies worldwide, including the U.S. Food and Drug Administration (FDA).

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 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, 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 [LinkedIn](#).

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373 and NanoFlu, its COVID-seasonal influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, 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.

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<https://ir.novavax.com/2022-02-14-Novavax-Files-for-Conditional-Marketing-Authorization-of-COVID-19-Vaccine-in-Switzerland>