

# Novavax and SK bioscience Expand Manufacturing Agreement

December 23, 2021

GAITHERSBURG, Md., Dec. 23, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, and SK bioscience, Co. Limited, a vaccine business subsidiary of Korea-based SK Group, today announced the expansion of the companies' collaboration and license agreements for NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine.

The companies have agreed that SK bioscience will reserve significant additional manufacturing capacity to produce antigen, a key component of NVX-CoV2373, through 2022, with the possibility to extend the arrangement. The agreement between the companies also builds on a previously announced advance purchase agreement (APA) between SK bioscience and the Korean government to supply 40 million doses of NVX-CoV2373 for the Republic of Korea. SK bioscience may supply additional quantities of NVX-CoV2373 in the Korean market in 2022. Additionally, SK bioscience has acquired non-exclusive rights to sell doses of Novavax' vaccine to the governments of Thailand and Vietnam.

"SK bioscience and the Korean government continue to be significant partners with Novavax in our efforts to ensure broad access of our COVID-19 vaccine to the citizens of South Korea and beyond," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This strategic partnership helps to further expand our global network for manufacture and commercialization of high-quality product and will be an important part of our expected 2 billion annual doses in total global manufacturing capacity in 2022."

"SK bioscience shares Novavax' sense of urgency to deliver a safe and effective protein-based COVID-19 vaccine to help protect not only South Koreans, but also the global population," said Jaeyong Ahn, Chief Executive Officer, SK bioscience. "We are committed to supporting the production of NVX-CoV2373 in South Korea and doing our part in the fight against COVID-19 in partnership with Novavax."

In collaboration with Novavax, SK bioscience initiated the rolling submission process for NVX-CoV2373 with South Korea's Ministry of Food and Drug Safety (MFDS) in April. A biologics license application was submitted to the MFDS in [November](#). Additional information regarding Novavax' previous licensing agreement with SK bioscience is available [here](#).

## 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. The current assigned shelf-life of the vaccine is 9 months.

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. Full results of the trial were published in the [New England Journal of Medicine \(NEJM\)](#).

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 7 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. 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 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 Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, 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](http://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, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and Novavax' expected global manufacturing capacity 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](http://www.sec.gov) and [www.novavax.com](http://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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