# Novavax Announces Submission of New Drug Application in Japan for Approval of COVID-19 Vaccine

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GAITHERSBURG, Md., Dec. 15, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the submission of a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare (MHLW) in Japan for its COVID-19 vaccine by its partner Takeda Pharmaceutical Company Limited (Takeda). Novavax' recombinant nanoparticle COVID-19 vaccine with Matrix-M™ adjuvant, known as TAK-019 in Japan and NVX-CoV2373 outside Japan, is the first protein-based COVID-19 vaccine to be submitted under an NDA in Japan.

With the support of the MHLW, the companies are working to establish the capability to manufacture TAK-019 at Takeda's facilities in Japan and aim to begin distribution in early 2022, pending regulatory approval.

"Today's submission marks further progress in our quest to ensure broad global access to our protein-based COVID-19 vaccine," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "Our partnership with Takeda reflects our shared commitment to tireless collaboration to deliver a COVID-19 vaccine, built on a well-understood vaccine platform."

The NDA submission includes an interim analysis from Takeda's ongoing Phase 1/2 immunogenicity and safety clinical trial of NVX-CoV2373/TAK-019 in Japan, in which the vaccine demonstrated a robust immune response and was well tolerated with no serious adverse events. Takeda submitted all available chemistry, manufacturing and controls (CMC), non-clinical and clinical data as of December 2021. Additional CMC data will be subsequently submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) during the NDA review period.

The application also includes safety and efficacy data from Novavax' two pivotal Phase 3 trials: PREVENT-19, which included 30,000 participants in the U.S. and Mexico and demonstrated 100% protection against moderate and severe disease, 93.2% efficacy against the predominantly circulating variants of concern and variants of interest, and 90.4% efficacy overall; and a trial of 15,000 participants 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. In both trials, NVX-CoV2373 demonstrated a reassuring safety and tolerability profile.

In addition to the submission of the NDA to MHLW in Japan, Novavax and Serum Institute of India Pvt. Ltd. (SII) recently received Emergency Use Authorization (EUA) for the vaccine in Indonesia and the Philippines, and the companies have filed for EUA in India and for Emergency Use Listing (EUL) with the World Health Organization (WHO). Novavax also announced regulatory filings for its vaccine in the United Kingdom, Australia, New Zealand, Canada, Singapore, United Arab Emirates, and the European Union and with the WHO. Additionally, Novavax and SK bioscience announced a Biologics License Application (BLA) submission to MFDS in South Korea. Novavax expects to submit its complete CMC data package to the U.S. FDA by the end of the year.

**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.

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.

**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, the capability to manufacture TAK-019 at Takeda's facilities in Japan and aim to begin distribution in early 2022, Novavax' quest to ensure broad global access of its protein-based COVID-19 vaccine, Novavax' plans to deliver a COVID-19 vaccine to people around the globe, Novavax' plan to supplement the CMC data submitted to the PMDA with additional CMC data, and Novavax' plans to submit a complete CMC data package to the U.S. FDA by the end of the year 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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