Novavax Announces Submission of Biologics License Application in South Korea for Approval of NVX-CoV2373

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SK bioscience submits application for NVX-CoV2373, the first protein-based COVID-19 vaccine candidate for BLA, to South Korea's MFDS

GAITHERSBURG, Md., Nov. 15, 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 (SK bioscience), a biotechnology company in South Korea, today announced the submission of a Biologics License Application (BLA) for Novavax' COVID-19 vaccine to South Korea's Ministry of Food and Drug Safety (MFDS). NVX-CoV2373, Novavax' recombinant nanoparticle COVID-19 vaccine with Matrix-M™ adjuvant, is the first protein-based COVID-19 vaccine to be submitted for BLA in Korea.

"Today's submission reflects the first BLA submission for full approval of our COVID-19 vaccine anywhere in the world, with more anticipated to follow," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Our partnership with SK bioscience reinforces our shared commitment to global equitable access as we work together to deliver our COVID-19 vaccine, built on a proven, well-understood vaccine platform."

In collaboration with Novavax, SK bioscience initiated the rolling submission process for NVX-CoV2373 to the MFDS in April of this year. The completion of a BLA submission to the MFDS marks the final review stage for authorization of NVX-CoV2373 in Korea.

Novavax and SK bioscience have an existing manufacturing and licensing collaboration that is intended to provide broad and equitable access to NVX-CoV2373 both in Korea and globally through the COVAX Facility. SK bioscience finalized an advance purchase agreement with the Korean government to supply 40 million doses of NVX-CoV2373 to South Korea earlier this year.

"Novavax' protein-based vaccine will be a new cornerstone in overcoming the COVID-19 pandemic," said Jaeyong Ahn, Chief Executive Officer, SK bioscience. "We are proud to collaborate in process development and production of Novavax' COVID-19 vaccine candidate in South Korea and are committed to doing our part in the fight against COVID-19."

Novavax recently announced authorization of its vaccine in Indonesia. The company also announced regulatory filings for its vaccine in the United Kingdom, Australia, New Zealand and Canada, as well as the complete submission of all data and modules in the European Union to support the final regulatory review of its dossier by the European Medicines Agency. Novavax and the Serum Institute of India also announced filings in India and the Philippines in August. Novavax expects to submit the complete package to the U.S. FDA by the end of the year.

About the NVX-CoV2373 Phase 3 Trials
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial 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; and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It was generally well-tolerated and elicited a robust antibody response.

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 microgram antigen and 50 microgram 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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both 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 on Twitter and 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 other Novavax vaccine product candidates, the scope, timing and outcome of future regulatory filings and actions and Novavax' anticipated role in fighting the COVID-19 pandemic 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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