Novavax Investor Relations

-- Application marks the first protein-based COVID-19 vaccine submitted to regulatory authorities for provisional approval in Australia

-- In addition to today's submission to the Therapeutic Goods Administration, the company recently filed for authorization with MHRA, with additional filings in process

-- All modules required for Australian regulatory evaluation, including Quality/ CMC data, are now complete

GAITHERSBURG, Md., Oct. 29, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the completion of its rolling submission to the Therapeutic Goods Administration (TGA) for provisional approval of its COVID-19 vaccine candidate. The company's application to the TGA marks the first complete application for provisional approval of a protein-based COVID-19 vaccine in Australia.

"This submission brings Novavax significantly closer to delivering doses of the first protein-based COVID-19 vaccine to Australia and, along with this week's filing for conditional marketing authorization in the U.K., brings us one step closer to our goal of ensuring broad global access to our vaccine," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the Australian clinical trial participants and trial sites, as well as the regulatory and vaccine experts, for their assistance and contribution to this vaccine program."

Australia has played a pivotal role in the Phase 1 and Phase 2 clinical trials supporting the development of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. Additional booster trials and a Phase 1/2 trial for a combination vaccine using Novavax' seasonal influenza and COVID-19 vaccine are underway in Australia.

Novavax has now completed the submission of all modules required by the TGA for the regulatory evaluation of its COVID-19 vaccine. This includes preclinical, clinical, and chemistry, manufacturing and controls (CMC) data. Clinical data from a pivotal Phase 3 trial of 15,000 participants in the U.K. was submitted to the TGA earlier this year in which NVX-CoV2373 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, as well as a favorable safety and tolerability profile. Clinical data from PREVENT-19, a pivotal Phase 3 trial of 30,000 participants in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall, was also submitted to the TGA.

Novavax recently filed for conditional marketing authorization in the U.K. and expects to shortly complete additional regulatory filings in key markets, including Europe, Canada, New Zealand and the World Health Organization, as well as other markets around the world. In the U.S., Novavax expects to submit the complete package to the FDA by the end of the year.

This submission was facilitated by the Company's local partner, Biocelect Pty. Ltd., as sponsor. The submission to TGA leverages Novavax' manufacturing partnership with the Serum Institute of India, the world's largest supplier of COVID-19 vaccines, and will later be supplemented with additional global supply chain.

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 us 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 the preparedness of Novavax to deliver vaccine doses 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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