Novavax Investor Relations

- *Filing marks first protein-based COVID-19 vaccine submitted to MHRA for authorization*
- *All modules required for regulatory review, including CMC data, are now complete*
- *Submission based on Phase 3 data from ~45K patients demonstrating high efficacy and well-tolerated safety, including against variants*
- *Submissions to additional global regulatory authorities including EU, Canada and Australia expected soon*

GAITHERSBURG, Md., Oct. 27, 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 regulatory submission to the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for authorization of its COVID-19 vaccine candidate. The company's application for Conditional Marketing Authorization (CMA) marks the first submission for authorization of a protein-based COVID-19 vaccine in the United Kingdom.

"This submission brings Novavax significantly closer to delivering millions of doses of the first protein-based COVID-19 vaccine, built on a proven, well-understood vaccine platform that demonstrated high efficacy against multiple strains of the coronavirus," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We look forward to MHRA's review and will be prepared to deliver vaccine doses following what we anticipate will be a positive decision. We thank the clinical trial participants and trial sites in the United Kingdom, as well as the U.K. Vaccines Taskforce, for their support and vital contributions to this program."

Novavax has now completed the submission of all modules required by MHRA for the regulatory review of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. This includes preclinical, clinical, and chemistry, manufacturing and controls (CMC) data. Clinical data from a pivotal Phase 3 trial of 15,000 volunteers in the U.K. was submitted to MHRA 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. The submission also includes data from PREVENT-19, a 30,000-person trial in the U.S. and Mexico, which demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. NVX-CoV2373 was generally well-tolerated and elicited a robust antibody response.

Novavax expects to complete additional regulatory filings in key markets, including Europe, Canada, Australia, New Zealand, the World Health Organization and other markets around the world shortly following the U.K. submission. In the U.S., Novavax expects to submit the complete package to the FDA by the end of the year. The company continues to work closely with governments, regulatory authorities and non-governmental organizations (NGOs) in its commitment to ensuring equitable global access to its COVID-19 vaccine.

"The submission to MHRA leverages our manufacturing partnership with the Serum Institute of India, the world's largest supplier of COVID-19 vaccines," said Rick Crowley, Executive Vice President, Chief Operations Officer, Novavax. "In the near future, we expect to supplement this filing with supply from our global supply chain."

Click here to view multimedia content, including B-roll and other resources that accompany this press release.

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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