

# Novavax Files for COVID-19 Vaccine Authorization with Health Canada and Completes Submission for Rolling Review to European Medicines Agency

November 1, 2021

- *Health Canada filing marks first protein-based COVID-19 vaccine submitted for authorization to regulatory authorities in Canada*
- *Submission of all modules required for regulatory review, including CMC and clinical data, are now complete for European Medicines Agency*

GAITHERSBURG, Md., Nov. 1, 2021 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 Health Canada for authorization of its COVID-19 vaccine candidate, the first filing of a protein-based COVID-19 vaccine in Canada. In addition, the company has completed the submission of all data and modules to the European Medicines Agency (EMA) to support the final regulatory review of its dossier.

"Novavax continues to deliver regulatory filings that we expect will bring the first protein-based COVID-19 vaccine based on Phase 3 data to the world," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the Government of Canada and the European Commission for their ongoing partnership and confidence in our COVID-19 vaccine program."

Novavax has now completed the submission of all modules required by Health Canada and EMA for the regulatory evaluation of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. The final step to completing the application in the European Union will be an invitation from EMA to file for Conditional Marketing Authorization.

The chemistry, manufacturing and controls (CMC) data packages submitted to Health Canada and EMA, as well as other global regulatory agencies, leverage Novavax' manufacturing partnership with the Serum Institute of India Pvt. Ltd. (SII), the world's largest supplier of COVID-19 vaccines. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

The submissions also include 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. Clinical data from a pivotal Phase 3 trial of 15,000 participants in the U.K. were also previously submitted to the regulatory agencies, 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. In both trials, NVX-CoV2373 demonstrated a favorable safety and tolerability profile.

Novavax recently announced regulatory filings for its vaccine in the United Kingdom and Australia and expects to complete additional regulatory filings shortly in multiple additional markets, along with an additional supplemental filing for its vaccine for Emergency Use Listing (EUL) with the World Health Organization. Novavax expects to submit the complete 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 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](http://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](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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