Novavax Announces Start of Rolling Review by Multiple Regulatory Authorities for COVID-19 Vaccine Authorization

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GAITHERSBURG, Md., Feb. 04, 2021 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the start of the rolling review process for authorization of NVX-CoV2373, its COVID-19 vaccine, by multiple regulatory agencies. The reviews will continue while the company completes its pivotal Phase 3 trials in the United Kingdom (U.K.) and United States (U.S.) and through initial authorization for emergency use granted under country-specific regulations.

“The rolling review of our submission by regulatory authorities of non-clinical data and early clinical studies will help expedite the review process and bring us that much closer to delivering a safe and effective vaccine worldwide,” said Gregory M. Glenn, MD, President of Research and Development, Novavax. “We appreciate the agencies’ confidence in Novavax based on our early data and the collective sense of urgency to ensure speedier access to much-needed COVID-19 vaccination.”

To date, Novavax has begun the rolling review process with several regulatory agencies worldwide, including the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), U.K. Medicines and Healthcare products Regulatory Agency (MHRA), and Health Canada. As part of the rolling review, the company will continue to submit additional information, including clinical and manufacturing data.

Novavax’ recombinant protein-based vaccine candidate is currently in Phase 3 clinical development in both the U.K. and U.S. for the prevention of COVID-19. It was the first vaccine to demonstrate clinical efficacy against the original strain of COVID-19 and both of the rapidly emerging variants in the United Kingdom and South Africa.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence 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 adjuvanted with Novavax’ patented saponin-based Matrix-M™ 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. In preclinical studies, NVX-CoV2373 induced antibodies that block binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the U.K that demonstrated 89.3 percent overall efficacy and 95.6 percent against the original strain in a post-hoc analysis, and the PREVENT-19 trial in the U.S. and Mexico that began in December. It is also being tested in two ongoing Phase 2 studies that began in August: A Phase 2b trial in South Africa that demonstrated up to 60 percent efficacy against newly emerging escape variants, and a Phase 1/2 continuation in the U.S. and Australia.

About Matrix-M™
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 and will be advanced for regulatory submission. 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.

Novavax Forward Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading “Risk Factors” in the Novavax Annual Report on Form 10-K for the year ended December 31, 2019, and Quarterly Report on Form 10-Q for the period ended September 30, 2020, 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 sec.gov, 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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