

Novavax and Serum Institute of India Announce Development and Commercial Collaboration

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GAITHERSBURG, Md., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced a license agreement with Serum Institute of India Private Limited (SIPL) for the development and commercialization of NVX-CoV2373, Novavax' COVID-19 vaccine candidate, in low- and middle-income countries (LMIC) and India. This agreement excludes major upper-middle and high-income countries, for which Novavax continues to retain rights. NVX-CoV2373 is a stable, prefusion protein made using Novavax' recombinant protein nanoparticle technology and includes Novavax' proprietary Matrix-M™ adjuvant.

“Novavax is strongly committed to ensuring a global supply of NVX-CoV2373, including for low- and middle-income countries that are also significantly impacted by coronavirus,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “As the world's largest vaccine manufacturer in terms of doses delivered, Serum Institute is the ideal partner to advance NVX-CoV2373 throughout India and the LMIC countries. This partnership continues to build on our companies' collaborative history.”

For LMICs and India, Novavax and SIPL are partnering on clinical development, co-formulation, filling and finishing and commercialization of NVX-CoV2373. SIPL will be responsible for regulatory submissions and marketing authorizations. Novavax will provide to SIPL both vaccine antigen and Matrix-M adjuvant, and Novavax and SIPL are in discussions to have SIPL manufacture vaccine antigen in India. Novavax and SIPL will split the revenue from the sale of product, net of agreed costs.

“We believe that Novavax' NVX-CoV2373 has significant potential to successfully prevent COVID-19. Given our experience with Novavax on the development of a malaria vaccine, we know the power of their vaccine technologies,” said Adar Poonawalla, Chief Executive Officer of Serum Institute of India. “We will work urgently together to bring this vaccine to patients in these geographies.”

This agreement further boosts the global supply of the NVX-CoV2373 vaccine and builds on and complements Novavax' collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI). Through that partnership with CEPI, Novavax has committed to develop and manufacture significant amounts of NVX-CoV2373, if proved safe and effective, to be procured and distributed equitably by the COVAX Facility through a globally fair allocation framework.

About NVX-CoV2373

NVX-CoV2373 is a 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 contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX-CoV2373 demonstrated indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In its Phase 1 portion of the Phase 1/2 clinical trial, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Novavax was awarded \$1.6 billion by the federal government as part of Operation Warp Speed (OWS), a U.S. government program to deliver millions of doses of a safe, effective vaccine for COVID-19 to the U.S. population. The OWS funding is being used by Novavax to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373 beginning as early as late 2020. The Coalition for Epidemic Preparedness Innovations (CEPI) is also investing up to \$388 million, and Department of Defense (DoD) is investing up to \$60 million of funding to advance clinical development of NVX-CoV2373.

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 late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in its Phase 1 portion of the Phase 1/2 clinical trial. 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 in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

For more information, visit www.novavax.com and connect with us on [Twitter](#) and [LinkedIn](#).

About Serum Institute of India

Serum Institute of India Pvt. Ltd. was founded in 1966 by Dr. Cyrus Poonawalla with a mission of manufacturing life-saving immuno-biologics. Serum is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.3 billion doses). It is estimated that about 65% of the children in the world receive at least one vaccine manufactured by Serum Institute. Vaccines manufactured by Serum are accredited by the World Health Organization, Geneva and are being used in approximately 170 countries across the globe.

Serum is ranked as India's No. 1 biotechnology company, manufacturing highly specialized lifesaving biologics like vaccines using cutting edge genetic and cell-based technologies, antisera and other medical specialties.

The philanthropic philosophy of Serum continues with its work on newer vaccines and biologicals.

Learn more about Serum Institute of India at <https://www.seruminstitute.com/>.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil society organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 9 partnerships to develop vaccines against the novel coronavirus. The programs will leverage rapid response platforms already supported by CEPI as well as new partnerships. The aim is to advance COVID-19 vaccine candidates into clinical testing as quickly as possible.

Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).

Novavax Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products, including statements regarding the manufacturing of vaccine antigen dose amounts and timing, 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, as filed with the Securities and Exchange Commission (SEC) and updated by any Quarterly Report on Form 10-Q, particularly the risks inherent to developing novel vaccines. We caution investors not to place considerable reliance on the 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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