Novavax Announces COVID-19 Vaccine Manufacturing Agreement with Serum Institute of India, Increasing Novavax' Global Production Capacity to Over 2 Billion Doses Annually

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GAITHERSBURG, Md., Sept. 15, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced an amendment to its existing agreement with Serum Institute of India Private Limited (SIIPL) under which SIIPL will also manufacture the antigen component of NVX?CoV2373, Novavax' COVID?19 vaccine candidate. With this agreement, Novavax increases its manufacturing capacity of NVX-CoV2373 to over two billion doses annually, when all planned capacity has been brought online by mid-2021. NVX?CoV2373 is a stable, prefusion protein made using Novavax' recombinant protein nanoparticle technology and includes Novavax' proprietary Matrix?MTM adjuvant.

"Today's agreement with Serum Institute enhances Novavax' commitment to equitable global delivery of our COVID-19 vaccine. With this arrangement, we have now put in place a global supply chain that includes the recently acquired Praha Vaccines and partnerships with leading biologics manufacturers, enabling production on three continents," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "We continue to work with extraordinary urgency to develop our vaccine, now in Phase 2 clinical trials, and for which we anticipate starting Phase 3 efficacy trials around the world in the coming weeks."

The agreement with SIIPL augments a global supply chain that will deliver over two billion doses of NVX-CoV2373 annually as of 2021.

The antigen component of NVX-CoV2373 is being manufactured at Novavax CZ in Bohumil, Czech Republic (formerly Praha Vaccines), as well as at the following partnered manufacturing sites:

- Biofabri in Spain
- FUJIFILM Diosynth Biotechnologies (FDB) in both North Carolina and Texas in the United States
- FDB in the United Kingdom
- SIIPL in India
- SK Bioscience in the Republic of Korea
- Takeda Pharmaceutical Company Limited in Japan

Novavax' Matrix-M adjuvant is now being manufactured at Novavax AB in Uppsala, Sweden and the following partnered manufacturing sites:

- AGC Biologics in the United States and Denmark
- PolyPeptide Group will manufacture two key intermediaries used in Matrix-M in the United States and Sweden

"Signing of the manufacturing agreement with Novavax for NVX-CoV2373 is another great milestone for both companies, which will further strengthen our existing relationship. SIIPL expertise to scale-up and manufacture NVX-CoV2373 will help ensure the supply of this most-needed vaccine," said Adar Poonawalla, Chief Executive Officer of Serum Institute of India.

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-MTM 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. Phase 2 clinical trials began in August 2020. Novavax has secured \$2 billion in funding for its global coronavirus vaccine program,

including up to \$388 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

About Matrix-MTM

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. 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 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 8-K for the period ended June 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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