Novavax and SK bioscience Announce Collaboration for Novavax' COVID-19 Vaccine Candidate

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GAITHERSBURG, Md. and SEOUL, South Korea, Aug. 13, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, and SK bioscience, a vaccine business subsidiary of SK Group, today announced a development and supply agreement for the antigen component of NVX-CoV2373, Novavax' COVID-19 vaccine candidate, for supply to global markets including the COVAX Facility. In addition, the companies have signed a letter of intent with the Republic of Korea's Ministry of Health and Welfare to work toward broad and equitable access to NVX-CoV2373 for the global market as well as to make the vaccine available in South Korea.

Under the terms of the agreement, SK bioscience will manufacture the vaccine antigen component for use in the final drug product globally during the pandemic period.

NVX-CoV2373 was developed using Novavax' recombinant nanoparticle technology to generate a stable, prefusion antigen derived from the coronavirus spike (S) protein. It contains Novavax' patented saponin-based Matrix-MTM adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. Phase 1 data from the Company's Phase 1/2 randomized, observer-blinded, placebo-controlled trial shows that NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera.

SK bioscience, using its cell culture and recombinant protein capability, will initiate the production of the NVX-CoV2373 antigen at its vaccine facility in Andong L-house, South Korea beginning in August 2020.

This contract development and manufacturing organization agreement leverages the capacity reservation agreement between SK bioscience and the Coalition for Epidemic Preparedness Innovations (CEPI). Novavax' NVX-CoV2373 will be manufactured using a part of the reserved capacity at SK Bioscience's "L-House" facility.

This agreement further boosts the potential global supply of the NVX-CoV2373 vaccine and is an important component of Novavax' collaboration with CEPI. Through that partnership with CEPI, Novavax has committed to develop and manufacture significant amounts of NVX-CoV2373, including vaccine derived from antigen coming from SK bioscience, if proved safe and effective, to be procured and distributed by the COVAX Facility through a globally fair allocation framework.

"We are proud to partner with SK bioscience to fulfill our commitment to ensure global supply of NVX-CoV2373 in alignment with our partnership with CEPI," said Stanley C. Erck, President and CEO of Novavax. "SK bioscience shares our sense of urgency to ensure broad and equitable access for our COVID-19 vaccine candidate around the world."

Jaeyong Ahn, CEO of SK bioscience said, "SK's accumulated vaccine R&D and production capability has been spotlighted by the world's most advanced global pharmaceutical companies as well as the global initiatives for the COVID-19 vaccine manufacturing and supply such as CEPI." He added, "We will cooperate with the government supporting its two-track strategy, developing vaccine in Korea and securing COVID-19 vaccine from a global manufacturer in a short period of time."

For further information, including media-ready images, b-roll, downloadable resources and more, click here.

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 data 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 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^{TM} 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 data of the Phase 1/2 clinical trial. NanoFluTM, 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-MTM 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 SK bioscience

SK bioscience is an innovative South Korean biopharmaceutical company specialized in the vaccine area. SK bioscience developed the cell-culture based influenza vaccine named SKYCellFluTM prequalified by WHO in 2019, SKYZosterTM, the world's second vaccine for shingles, and SKYVaricellaTM, the world's second WHO prequalified varicella vaccine for chicken pox. By leveraging the company's strengths on cutting-edge vaccine technologies, SK bioscience has been expanding its R&D portfolio including pneumococcal conjugate vaccine, human papillomavirus vaccine, typhoid conjugate vaccine and non-replicating rotavirus vaccine through in-house development or external partnership with public and private institutions around the globe pursuing global health. For the COVID-19 vaccine response, SK bioscience is undergoing development for its vaccine candidate against SARS-CoV-2 with support from the Bill and Melinda Gates Foundation.

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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