

Novavax and Commonwealth of Australia Announce Agreement in Principle for Acquisition of Novavax COVID-19 Vaccine

November 4, 2020

GAITHERSBURG, Md., Nov. 04, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the signing of a non-binding Heads of Terms document with the Australian Government to supply 40 million doses of the Company's COVID-19 vaccine candidate, NVX-CoV2373, for the Australian community.

"This arrangement with the Australian Government reflects the importance of the ongoing clinical development of NVX-CoV2373, and will ensure that the citizens of Australia will have access to its supply," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "We are pleased with the progress of our ongoing Phase 3 clinical trial in the UK, and are pressing forward to deliver efficacy data for NVX-CoV2373, with interim data in this event-driven trial expected as soon as early first quarter 2021."

The Heads of Terms provides for the delivery of NVX-CoV2373 to Australia starting as early as the first half of 2021, subject to the successful completion of Phase 3 clinical development and approval of the vaccine by Australia's Therapeutic Goods Administration (TGA). The vaccine regimen is expected to require two doses per individual, administered 21 days apart.

To date, Novavax has established various agreements for the supply of NVX-CoV2373 directly to the United States and the United Kingdom, Canada and now Australia, and through partnerships, supply to Japan, South Korea and India.

Australia's clinical trial contribution

Australia has played a pivotal role in the clinical development program for NVX-CoV2373. Australian clinical researchers led the global Phase 1 clinical trial in August. This trial involved 131 Australians across two trial sites (Melbourne and Brisbane). In addition, approximately 690 Australians have participated in the Phase 2 arm of the clinical trial, which has been conducted across up to 40 sites in Australia and the U.S.

The planned global Phase 3 clinical programs evaluating NVX-CoV2373 will assess immunity, safety and COVID-19 disease prevention. The trials seek to recruit members of the community most vulnerable to COVID-19 – the elderly, those with underlying medical conditions as well as diverse racial and ethnic representation.

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. NVX-CoV2373 contains purified protein antigen and cannot replicate, nor can it cause COVID-19. In preclinical trials, NVX-CoV2373 demonstrated induction of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In the Phase 1 portion of its 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. NVX-CoV2373 is also being evaluated in a Phase 3 trial in the UK and two ongoing Phase 2 studies that began in August; a Phase 2b trial in South Africa, and a Phase 1/2 continuation in the U.S. and Australia. 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-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 Manufacturing

Novavax is progressing large-scale manufacturing of NVX-CoV2373 across multiple locations around the world. Delivery of initial doses of the vaccine is expected as early as the end of this year, with the goal to expand the production to enable delivery of over 2 billion doses annually, once all production is online.

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 currently conducting multiple clinical trials for NVX-CoV2373, its vaccine candidate against the virus that causes COVID-19, including a pivotal Phase 3 clinical trial in the United Kingdom to evaluate the efficacy, safety and immunogenicity in individuals aged 18-84 years of age. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both candidate vaccines incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant 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](#).

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 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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