



Novavax and Takeda Finalize License Agreement for Novavax' COVID-19 Vaccine Candidate in Japan; Takeda Initiates Phase 1/2 Trial in Japan

February 26, 2021

- Agreement includes COVID-19 vaccine technology transfer to Takeda for local manufacturing and commercialization in Japan
- Takeda doses first participant in immunogenicity and safety study to support local regulatory application

GAITHERSBURG, Md., February 25, 2021 -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced progress in its collaboration with Takeda Pharmaceutical Company Limited, originally [announced](#) in August. The companies have signed an exclusive license agreement for Takeda's development, manufacturing and commercialization of NVX-CoV2373, Novavax' COVID -19 vaccine candidate, in Japan. Additionally, Takeda dosed the first participants in a Phase 1/2 clinical trial to test the immunogenicity and safety of Novavax' vaccine candidate in the Japanese population.

"This agreement progresses our collaboration with Takeda as we rapidly work together to make our vaccine candidate available in Japan," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "It is vital that we extend the reach and availability of vaccines like NVX-CoV2373 to stop the COVID-19 pandemic, and Takeda is well positioned to make that happen."

Novavax and Takeda are collaborating on manufacturing, clinical development and regulatory activities in Japan. Novavax will transfer the technology for manufacturing of the vaccine antigen and will supply its Matrix-M™ adjuvant to Takeda. Takeda anticipates the capacity to manufacture over 250 million doses of the COVID-19 vaccine per year. Novavax will be entitled to receive payments based on the achievement of certain development and commercial milestones, as well as a portion of proceeds from the vaccine.

In addition, Takeda has begun a placebo-controlled, observer-blinded Phase 1/2 study in Japan to evaluate the immunogenicity and safety of NVX-CoV2373 (known as TAK-019 in Japan) in 200 healthy volunteers aged 20 years and older. Participants will receive two doses of either vaccine or placebo 21 days apart and will be followed for 12 months following the second dose. Takeda is responsible for regulatory submission to Japan's Pharmaceutical and Medical Devices Agency (PMDA) and will manufacture and commercialize NVX-CoV2373 (TAK-019) in Japan.

Novavax has previously [reported](#) positive interim efficacy results of NVX-CoV2373, its recombinant protein-based vaccine candidate, in an ongoing Phase 3 clinical trial taking place in the United Kingdom.

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 50-60 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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