Novavax and Takeda Announce Collaboration for Novavax' COVID-19 Vaccine Candidate in Japan

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GAITHERSBURG, Md. and OSAKA, Japan, Aug. 07, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, and Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK), today announced a partnership for the development, manufacturing and commercialization of NVX?CoV2373, Novavax' COVID?19 vaccine candidate, in Japan. NVX?CoV2373 is a stable, prefusion protein made using Novavax' recombinant protein nanoparticle technology and includes Novavax' proprietary Matrix?M™ adjuvant. Takeda will receive funding from the Government of Japan's Ministry of Health, Labour and Welfare (MHLW) to support the technology transfer, establishment of infrastructure and scale-up of manufacturing. Takeda anticipates the capacity to manufacture over 250 million doses of the COVID-19 vaccine per year1.

"Takeda's leading position in Japan, technical expertise, regulatory know-how and manufacturing capacity make the company an ideal partner to further expand the global availability of NVX?CoV2373," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "We look forward to collaborating with Takeda to rapidly develop, produce and commercialize the vaccine in Japan."

Novavax and Takeda are partnering on manufacturing, clinical development and regulatory activities in Japan. Novavax will license and transfer manufacturing technologies to enable Takeda to manufacture the vaccine antigen and will supply the Matrix-M adjuvant to Takeda. Takeda will be responsible for regulatory submission to the MHLW and will produce and distribute NVX?CoV2373 in Japan.

"Nothing is more important right now than protecting the world against COVID-19. We are excited to collaborate with Novavax to bring their promising vaccine candidate to Japan," said Rajeev Venkayya, M.D., President of the Global Vaccine Business Unit, Takeda. "Today's announcement builds upon our ongoing support of pandemic preparedness and demonstrates Takeda's commitment to the health and well-being of the Japanese population."

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.

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 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 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 data 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 Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries.
For more information, visit https://www.takeda.com.

Takeda's Commitment to Vaccines

Vaccines prevent 2 to 3 million deaths each year and have transformed global public health. For the past 70 years, Takeda has supplied vaccines to protect the health of people in Japan. Today, Takeda's global vaccine business is applying innovation to tackle some of the world's most challenging infectious diseases, such as dengue, Zika and norovirus. Takeda's team brings an outstanding track record and a wealth of knowledge in vaccine development, manufacturing and global access to advance a pipeline of vaccines to address some of the world's most pressing public health needs. For more information, visit www.TakedaVaccines.com.

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 rights and responsibilities of each of Novavax and Takeda in their partnership, plans related to manufacturing [(including vaccine antigen dose amounts)], development, regulatory and commercial activities in Japan, potential payments to Novavax from Takeda, Novavax' expectations of third-party funding and anticipated timing of Novavax' clinical trial results are forward-looking statements. These statements may be identified by words such as "expect," "look forward," "potential," "will" and similar references to future periods. 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 uncertainty of success in the development and potential commercialization of NVX-CoV2373, unexpected delays in clinical trials or regulatory review of NVX-CoV2373, potential set backs in scaling up manufacturing of NVX-CoV2373, adverse impacts of the ongoing COVID-19 pandemic on Novavax' business, Novavax' future capital requirements and availability of funding, as well as those risks 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. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. 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.

Takeda Pharmaceutical Company Limited Forward-Looking Statements

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results

to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: https://www.takeda.com/investors/reports/sec-filings/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

Contacts:

Novavax

Investors
Silvia Taylor and Erika Trahan
ir@novavax.com
240-268-2022

Media
Brandzone/KOGS Communication
Edna Kaplan
kaplan@kogspr.com
617-974-8659

Takeda Pharmaceuticals

Media in Japan
Kazumi Kobayashi
+81 (0) 3-3278-2095
kazumi.kobayashi@takeda.com

Media Outside Japan
Amy Atwood
+1 774-571-3316
amy.atwood@takeda.com

1. The projected capacity is an estimate only based on current assumptions from Novavax.