Novavax to Receive up to $388 Million Funding from CEPI for COVID-19 Vaccine Development and Manufacturing

May 11, 2020

- Funds clinical development of NVX-CoV2373 through Phase 2
- Supports rapid scale-up of vaccine manufacturing
- Allows for increased production of Matrix-M adjuvant
- Reserves global large-scale manufacturing capacity

GAITHERSBURG, Md., May 11, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that the Coalition for Epidemic Preparedness Innovations (CEPI) will invest up to $384 million of additional funding, on top of $4 million it invested in March, to advance clinical development of NVX-CoV2373, Novavax' coronavirus vaccine candidate against SARS-CoV-2. The additional funding from CEPI will also support rapid scale-up of the NVX-CoV2373 vaccine antigen, as well as Novavax' proprietary Matrix-M™ adjuvant, which is expected to enhance immune responses by stimulating high levels of neutralizing antibodies. In addition, the CEPI funding will allow Novavax to dramatically increase its large-scale manufacturing capacity for both antigen and adjuvant in multiple locations.

“CEPI plays a vital role in advancing innovative technologies against the COVID-19 pandemic. Their partnership and support allows Novavax to leverage its innovative vaccine platform and expertise in this global crisis,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “For the last few months, the entire Novavax team has been working nonstop in an ongoing effort to make our vaccine a reality, and we appreciate CEPI's confidence in our technology platform and our progress.”

Novavax plans to use CEPI funding to advance NVX-CoV2373 with:

- A Phase 1/2 clinical trial with the Phase I portion starting this month in Australia and the Phase 2 portion conducted in multiple countries following successful Phase 1 top-line results that are expected in July.
- Process development for scaled-up production to potentially allow manufacturing of up to 100 million vaccine doses by end of 2020.
- Access to large-scale manufacturing capacity in multiple countries with a goal of potentially producing over one billion doses during 2021.

Novavax and CEPI agree on the importance of global equitable access to the vaccines produced out of the partnership. It is anticipated that vaccines will be procured and allocated through global mechanisms now under discussion as part of the Access to COVID-19 Tools (ACT) Accelerator, an international initiative launched by the WHO and global leaders earlier this month.

“The expansion of our partnership with Novavax represents CEPI's single biggest investment to date”, said Richard Hatchett, Chief Executive Officer of CEPI. “Our vaccine R&D programmes are starting to show progress, so it is vital that we invest now to boost manufacturing capacity, so that our partners have the ability to produce vaccines at a global scale. We still have a long way to go, but we’re making important steps forward to deliver a safe, effective, and globally accessible vaccine as quickly as possible.”

About Coronavirus

SARS-CoV-2 first appeared in late 2019 in China before beginning its rapid spread across the globe. The disease, named COVID-19, continues to cause severe pneumonia-like symptoms in many of those infected. Coronaviruses, so named for their “crown-like” appearance, are a large family of viruses that are believed to have spread from animals to humans and include the viruses causing SARS (severe acute respiratory syndrome) and MERS (Middle East respiratory syndrome). While much remains unknown about the latest coronavirus, it is known to spread via human-to-human transmission before symptoms appear.

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 and helping an immunized person make antibodies against the virus.

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).

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 and address urgent, global health needs. Novavax recently initiated development of NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19, with Phase 1 clinical trial results expected in July of 2020. 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.

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, as filed with the Securities and Exchange Commission (SEC). 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.

Contacts:

Investors
Novavax, Inc.
Erika Trahan
ir@novavax.com
240-268-2022

Westwicke
John Woolford
john.woolford@westwicke.com
443-213-0506

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

Source: Novavax, Inc.