COVID-19 is an emerging, rapidly evolving situation.

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NEWS RELEASES

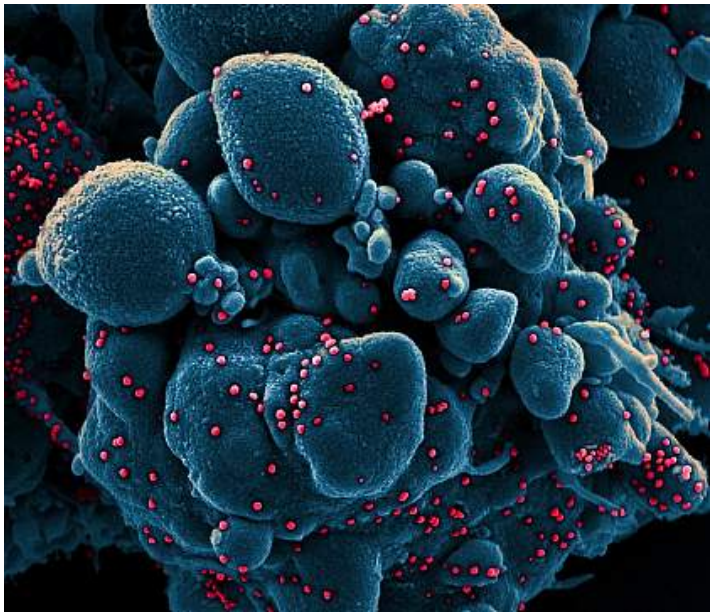
Monday, December 28, 2020

Phase 3 trial of Novavax investigational COVID-19 vaccine opens

NIH- and BARDA-funded trial will enroll up to 30,000 volunteers.

People 18 years of age and older who are interested in participating in this trial can visit coronaviruspreventionnetwork.org, ClinicalTrials.gov and search identifier NCT04611802, or Novavax.com/PREVENT-19 for details. Please do not contact the NIAID media phone number or email to enroll in this trial.

The Phase 3 trial of another investigational coronavirus disease 2019 (COVID-19) vaccine has begun enrolling adult volunteers. The randomized, placebo-controlled trial will enroll approximately 30,000 people at approximately 115 sites in the United States and Mexico. It will evaluate the safety and efficacy of NVX-CoV2373, a vaccine candidate developed by Novavax, Inc., of Gaithersburg, Maryland. Novavax is leading the trial as the regulatory sponsor. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, are funding the trial.



Colorized scanning electron micrograph of an apoptotic cell (blue) infected with SARS-COV-2 virus particles (red), isolated from a patient sample. *NIAID*

"Addressing the unprecedented health crisis of COVID-19 has required extraordinary efforts on the part of government, academia, industry and the community," said NIAID Director Anthony S. Fauci, M.D. "The launch of this study — the fifth investigational COVID-19 vaccine candidate to be tested in a Phase 3 trial in the United States — demonstrates our resolve to end the pandemic through development of multiple safe and effective vaccines."

The trial is being conducted in collaboration with Operation Warp Speed (OWS), a multi-agency collaboration overseen by HHS and the Department of Defense that aims to accelerate development, manufacture and distribution of medical countermeasures for COVID-19. Some of the U.S. trial sites participating are part of the NIAID-supported COVID-19 Prevention Network (CoVPN). The CoVPN includes existing NIAID-supported clinical research networks with infectious disease expertise and was designed for rapid and thorough evaluation of vaccine candidates and monoclonal antibodies for preventing COVID-19.

Volunteers will be asked to give informed consent prior to their participation in the trial. They will be grouped into two cohorts: individuals 18 through 64 years old and those aged 65 and older, with a goal of enrolling at least 25% of all volunteers who are 65 years

old or older. Trial organizers also are emphasizing recruitment of people who are at higher risk of severe COVID-19 disease, including those who are Black (including African Americans), Native American, or of Latino or Hispanic ethnicity, and people who have underlying health conditions such as obesity, chronic kidney disease or diabetes.

"We've come this far, this fast, but we need to get to the finish line," said NIH Director Francis S. Collins, M.D., Ph.D. "That will require multiple vaccines using different approaches to ensure everyone is protected safely and effectively from this deadly disease."

After providing a baseline nasopharyngeal and blood sample, participants will be assigned at random to receive an intramuscular injection of either the investigational vaccine or a saline placebo. Randomization will be in a 2:1 ratio with two volunteers receiving the investigational vaccine for each one who receives placebo. Because the trial is blinded, neither investigators nor participants will know who is receiving the candidate vaccine. A second injection will be administered 21 days after the first.

Participants will be followed closely for potential vaccine side effects and will be asked to provide blood samples at specified time points after each injection and during the following two years. Scientists will analyze the blood samples to detect and quantify immune responses to SARS-CoV-2, the virus that causes COVID-19. Of note, specialized assays will be used to distinguish between immunity as a result of natural infection and vaccine-induced immunity. The trial's primary endpoint is to determine whether NVX-CoV2373 can prevent symptomatic COVID-19 disease seven or more days after the second injection relative to placebo.

Novavax's investigational vaccine, NVX-CoV2373, is made from a stabilized form of the coronavirus spike protein using the company's recombinant protein nanoparticle technology. The purified protein antigens in the vaccine cannot replicate and cannot cause COVID-19. The vaccine also contains a proprietary adjuvant, MatrixM™. Adjuvants are additives that enhance desired immune system responses to vaccine. NVX-CoV2373 is administered in liquid form and can be stored, handled and distributed at above-freezing temperatures (35° to 46°F). A single vaccine dose contains 5 micrograms (mcg) of protein and 50 mcg of adjuvant.

In animal tests, NVX-CoV2373 vaccination produced antibodies that blocked the coronavirus spike protein from binding to the cell surface receptors targeted by the virus, preventing viral infection. In results of a Phase 1 clinical trial published in the *New England Journal of Medicine*, NVX-CoV2373 was generally well-tolerated and elicited higher levels of antibodies than those seen in blood samples drawn from people who had recovered from clinically significant COVID-19. NVX-CoV2373 also is being evaluated in a Phase 2b trial in South Africa, now fully enrolled with 4,422 volunteers, and data from a Phase 1/2 continuation trial in the United States and Australia is expected as early as first quarter 2021. Novavax also recently completed enrollment of more than 15,000 volunteers in a Phase 3 trial of the candidate vaccine in the United Kingdom, which is also testing two injections of 5 mcg of protein and 50 mcg of Matrix-M adjuvant administered 21 days apart.

An independent Data and Safety Monitoring Board (DSMB) will provide oversight to ensure the safe and ethical conduct of the study. All Phase 3 clinical trials of candidate vaccines supported through OWS are overseen by a common DSMB developed in consultation with the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative.

Adults who are interested in joining this study can visit Coronaviruspreventionnetwork.org, Novavax.com/PREVENT-19 or ClinicalTrials.gov and search identifier NCT04611802.

About the COVID-19 Prevention Network: The COVID-19 Prevention Network (CoVPN) was formed by the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health to respond to the global pandemic. Through the CoVPN, NIAID is leveraging the infectious disease expertise of its existing research networks and global partners to address the pressing need for vaccines and antibodies against SARS-CoV-2. CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of vaccines and antibodies for the prevention of COVID-19. The CoVPN is headquartered at the Fred Hutchinson Cancer Research Center. For more information about the CoVPN, visit: coronaviruspreventionnetwork.org.

About HHS, ASPR, and BARDA: HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, BARDA-supported products have achieved 55 FDA approvals, licensures or clearances. To learn more about federal support for the nationwide COVID-19 response, visit www.coronavirus.gov.

About Operation Warp Speed: OWS is a partnership among components of the Department of Health and Human Services and the Department of Defense, engaging with private firms and other federal agencies, and coordinating among existing HHS-wide efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

About the National Institute of Allergy and Infectious Diseases: NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID website.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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