U.S. clinical trial results show Novavax vaccine is safe and prevents COVID-19

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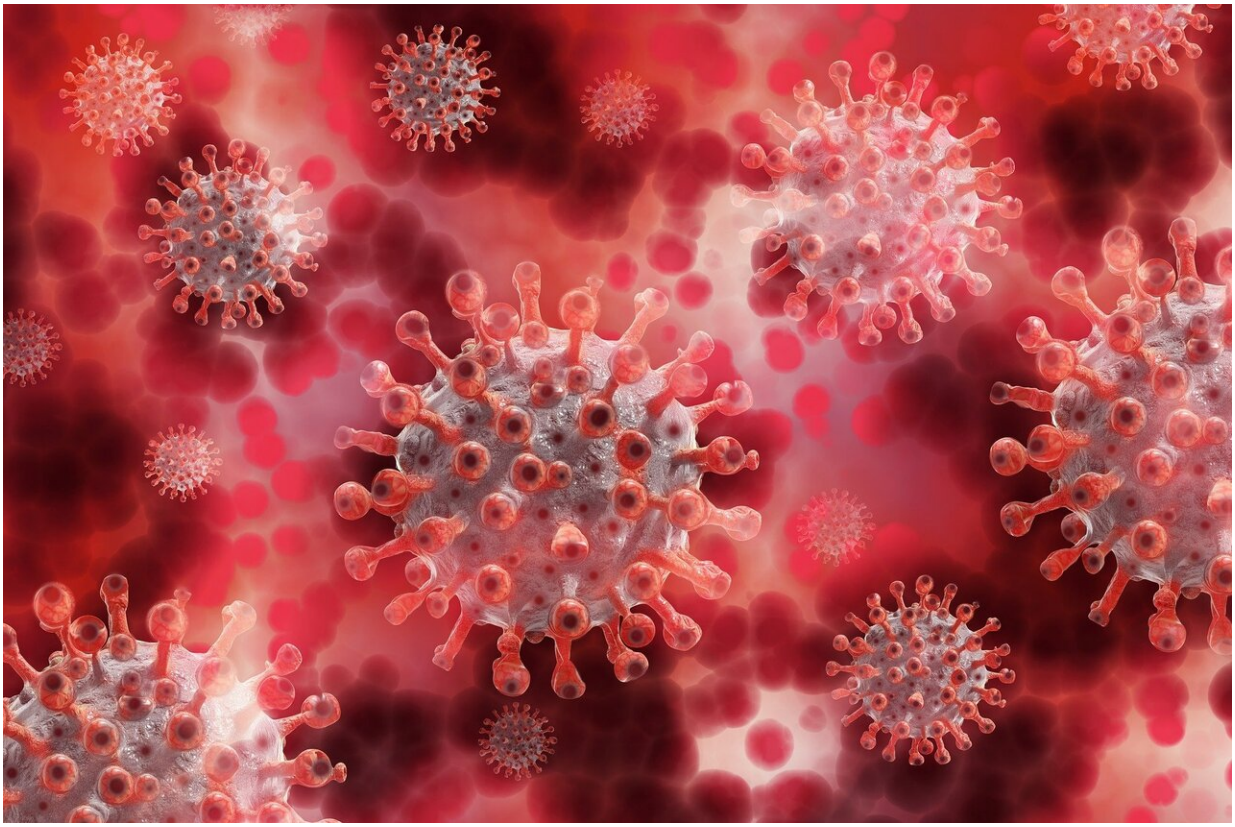

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Results from a Phase 3 clinical trial enrolling 29,960 adult volunteers in the United States and Mexico show that the investigational vaccine known as NVX-CoV2373 demonstrated 90.4% efficacy in preventing

symptomatic COVID-19 disease. The candidate showed 100% protection against moderate and severe disease. In people at high risk of developing complications from COVID-19 (people 65 years or older and people under age 65 with certain comorbidities or with likely regular exposure to COVID-19), the vaccine showed 91.0% efficacy in preventing symptomatic COVID-19 disease.

Safety data indicate the investigational vaccine was generally well-tolerated. Mild-to-moderate injection site pain and tenderness were the most common local symptoms among participants, and fatigue, headache and muscle pain lasting less than two days were the most common systemic symptoms.

Novavax, Inc., of Gaithersburg, Maryland, developed the investigational vaccine and led the clinical trial known as PREVENT-19. The Biomedical Advanced Research and Development Authority (BARDA), a component of the HHS Office of the Assistant Secretary for Preparedness and Response, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, provided funding support for the trial as part of the federal COVID-19 response.

The PREVENT-19 trial began in late December 2020 and enrolled adult volunteers at 119 study sites, including those in the NIAID-supported COVID-19 Prevention Network (CoVPN). Participants were randomly assigned to receive two shots, 21 days apart, of either the investigational vaccine or a saline placebo. Randomization occurred in a 2:1 ratio with two volunteers receiving NVX-CoV2373 for each one who received placebo. Because the trial was blinded, neither investigators nor participants knew who received the candidate vaccine.

PREVENT-19 was designed to evaluate whether NVX-CoV2373 can prevent symptomatic COVID-19 disease seven or more days after the

second injection relative to placebo. The results shared today are based on 77 cases of symptomatic COVID-19 that investigators observed among trial participants from January 25 through April 30, 2021. Investigators recorded 63 cases among the approximately 10,000 participants who received placebo and 14 cases among the approximately 20,000 participants who received the investigational vaccine. Of the 63 COVID-19 cases in the placebo group, investigators classified 10 as moderate and four as severe. There were no cases of moderate or severe disease in the investigational vaccine group.

NVX-CoV2373 is a subunit vaccine 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 or 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 by injection 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. The vaccine is administered as two intramuscular injections 21 days apart. The technology used for this vaccine was developed under a long-standing contract with the Department of Defense.

Results from a Phase 3 clinical trial enrolling 15,000 adults in the United Kingdom showed a two-dose regimen of NVX-CoV2373 was highly effective in preventing symptomatic COVID-19 overall and also demonstrated high efficacy against the Alpha variant strain of SARS-CoV-2.

An independent Data and Safety Monitoring Board (DSMB) is overseeing PREVENT-19 to ensure the safe and ethical conduct of the study. All Phase 3 clinical trials of candidate vaccines supported through the federal COVID-19 response are overseen by a common DSMB

convened by NIAID.

More information: Paul T. Heath et al, Efficacy of the NVX-CoV2373 Covid-19 Vaccine Against the B.1.1.7 Variant, *medRxiv* (2021). DOI: 10.1101/2021.05.13.21256639