Wednesday, July 20, 2022

Statement from NIH and BARDA on the Novavax COVID-19 Vaccine

A PREVENT-19 Phase 3 clinical trial volunteer receives a vaccine. *Novavax*

The Centers for Disease Control and Prevention (CDC) has recommended that Novavax's COVID-19 vaccine be used as another primary series option for adults in the United States ages 18 years and older. The Food and Drug Administration (FDA) previously authorized for emergency use the protein-based vaccine, known as NVX-CoV2373.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health; 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; the Department of Defense (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and

Nuclear Defense (JPEO-CBRND); and the Defense Health Agency supported the development of NVX-CoV2373 as part of the U.S. government's rapid response to develop safe and effective COVID-19 vaccines.

DoD funded the early development of technology used in the NVX-CoV2373 vaccine, and NIAID, BARDA, JPEO-CBRND and DoD provided support for clinical trials evaluating its safety and efficacy. BARDA also provided funding and expertise to support manufacturing and procurement of the vaccine.

NVX-CoV2373 contains a stabilized form of the SARS-CoV-2 spike protein—a surface protein that facilitates entry to human cells. The approach for stabilizing the spike protein was invented by NIAID scientists and their collaborators. The spike proteins are organized in tiny protein particles called nanoparticles. The vaccine is formulated with a saponin-based adjuvant. Saponins are naturally occurring compounds from soapbark trees. Adjuvants are sometimes added to vaccines to enhance immune responses.

The U.S. government supported the Phase 3 clinical trial known as PREVENT-19 that enrolled 29,960 adult participants in the United States and Mexico between Dec. 27, 2020, and Feb. 18, 2021. Participants were randomly assigned to receive two doses of the candidate vaccine 21 days apart or two injections of a saline placebo. Randomization occurred in a 2:1 ratio, with two volunteers receiving NVX-CoV2373 for each one who received placebo. Results published in the *New England Journal of Medicine* showed the candidate vaccine was 90.4% effective in preventing symptomatic COVID-19 among trial participants and 100% effective in preventing moderate-to-severe COVID-19. The trial was conducted before the Omicron variant of SARS-CoV-2 became dominant.

The PREVENT-19 trial expanded in May 2021 to enroll adolescents ages 12 to 17 years. Novavax has noted that the trial results in adolescents demonstrated comparability to those observed in the adult population. PREVENT-19 also is evaluating a third shot or booster dose in both adult and adolescent participants. In addition, NIAID is studying NVX-CoV2373 in the Phase 1/2 "mix & match" trial, in which adult volunteers who have been fully vaccinated against COVID-19 receive booster doses of different COVID-19 vaccines to determine the safety and immunogenicity of mixed boosted regimens.

Lawrence A. Tabak, D.D.S., Ph.D., Senior Official Performing the Duties of the NIH Director; Anthony S. Fauci, M.D., NIAID Director; and Gary Disbrow, Ph.D., BARDA Director, released the following statements:

"This is the third COVID-19 vaccine available in the U.S. as a result of the unprecedented government research response to develop safe and effective COVID-19 vaccines, for which NIH spearheaded the clinical testing. This collaborative approach involving many public-private partners provides an important blueprint for pandemic preparedness now and into the future." – Dr. Tabak

"People in the United States now have an additional COVID-19 vaccine available to them that offers protection against severe disease. The Novavax COVID-19 vaccine contains a SARS-CoV-2 protein and an adjuvant to boost the immune response. Other vaccines in routine use in the United States, including the hepatitis B vaccine, use this traditional protein-based platform. I continue to encourage all eligible adults and children to get vaccinated against COVID-19 and to stay up-to-date on boosters." – Dr. Fauci

"We are pleased to see this vaccine achieve FDA authorization, giving Americans another option for a vaccine to protect against COVID, particularly with cases on the rise again. Even with other FDA-approved vaccines available, we continue to support development of flexible vaccine technologies like this one so that we can respond more rapidly to future public health emergencies as well as the current health crisis." – Dr. Disbrow

Lawrence A. Tabak, D.D.S., Ph.D., is performing the duties of the Director of the National Institutes of Health in Bethesda, Maryland.

Anthony S. Fauci, M.D., is Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.

Gary Disbrow, Ph.D., is Director of the Biomedical Advanced Research and Development Authority (BARDA), in the HHS Office of the Assistant Secretary for Preparedness and Response.

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.

NIH...Turning Discovery Into Health®

References

LM Dunkle *et al.* Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico. *The New England Journal of Medicine* DOI: 10.1056/NEJMoa2116185 (2021).

###

Institute/Center

National Institute of Allergy and Infectious Diseases (NIAID)

Contact

NIAID News & Science Writing Branch
301-402-1663

Connect with Us

- Subscribe to news releases
- RSS Feed