Novavax COVID-19 vaccine found to be safe and effective

December 16 2021

Credit: Pixabay/CC0 Public Domain

An investigational COVID-19 vaccine made by Novavax was found to be 90 percent effective at preventing COVID-19 illness, according to results from a Phase 3 clinical trial published today in the *New England Journal of Medicine.* The University of Maryland School of Medicine's (UMSOM) Center for Vaccine Development and Global Health served

as one of the trial sites, and Karen Kotloff, MD, Professor of Pediatrics at UMSOM, served as Co-Chair for the trial protocol.

In the study, researchers recruited nearly 30,000 adult volunteers at 113 clinical sites in the United States and six sites in Mexico. Approximately 20,000 participants received two doses of the vaccine spaced three weeks apart and 10,000 received placebo. In addition to being highly effective in preventing COVID illness of any severity, the vaccine was 100 percent effective in preventing moderate and severe disease that required hospitalization.

During the first few months of 2021 when the study was conducted in the U.S. and Mexico, the predominant circulating strain was Alpha. The assessment did not include Delta or Omicron, the newest variant of concern, which had not begun to circulate.

Most side effects were mild to moderate and transient. Fever was very rare. The most common side effects in the vaccine recipients included pain and tenderness at the injection site, headache, muscle aches and fatigue that lasted a day on average. None of the recipients developed serious reactions like heart inflammation (myocarditis) or blood clots.

"Our study results indicate that this vaccine is highly efficacious and very safe. In addition, this vaccine has many attractive features. It is made from a small piece of protein, like many currently licensed vaccines in the U.S. and has convenient refrigerator storage requirements, so it will be an important addition to the COVID-19 vaccine portfolio, in the U.S. and in countries where supply is lacking," said Dr. Kotloff.

The UMSOM site enrolled nearly 500 participants over 18 of age. The participants were demographically diverse to reflect those in the general population at highest risk for infection and illness, including under-

represented minority groups who were disproportionately affected by the pandemic. About 12 percent of the study participants were in the high-risk group of those over age 65 years. About 27 percent of the study participants at UMSOM identified as Black, 19 percent Hispanic, 16 percent Asian, and 7 percent American Indian or Alaska Native.

Kathleen Neuzil, MD, MPH, FIDSA, the Myron M. Levine, MD, DTPH Professor of Vaccinology and Director, Center for Vaccine Development and Global Health (CVD) at UMSOM, and Monica McArthur, MD, Assistant Professor of Pediatrics, served as co-authors on this study.

The Novavax trial was part of Operation Warp Speed, a multi-agency collaboration led by the U.S. Department of Health and Human Services (HHS), which aims to accelerate the development, manufacturing and distribution of medical countermeasures for COVID-19. Novavax, based in Gaithersburg, MD, and the National Institute of Allergy and Infectious Disease also provided funding for the study.

"Throughout the pandemic, CVD has contributed to the advancement of several promising vaccine candidates. Our researchers worked meticulously and expeditiously to ensure that Americans and nations throughout the world had access to safe and effective vaccines to slow the pandemic and save lives," said E. Albert Reece, MD, Ph.D., MBA, Executive Vice President for Medical Affairs, UM Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine. "This latest study leads us a step closer to licensure of a new vaccine that will impact millions of people."

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