Novavax COVID-19 vaccine trial results show efficacy against the B.1.351 variant in SA study

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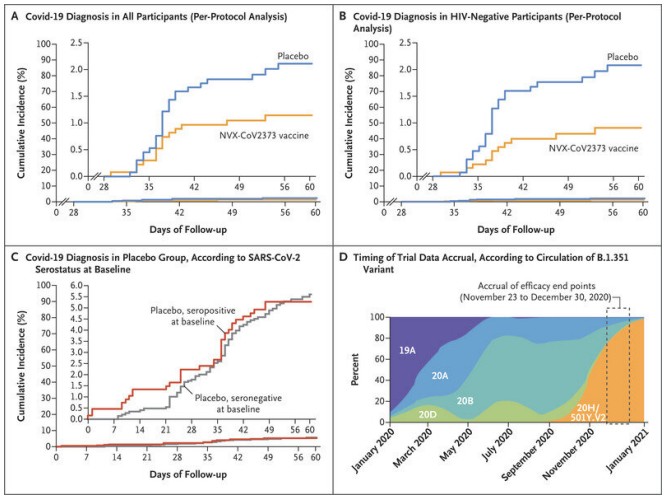

Kaplan–Meier Analysis of NVX-CoV2373 Efficacy against Symptomatic Covid-19 and Timing of Trial Data Accrual. Credit: *New England Journal of Medicine* (2021). DOI: 10.1056/NEJMoa2103055

The *New England Journal of Medicine* (*NEJM*) today published findings of the Phase 2b clinical trial conducted in South Africa.

Shabir Madhi, Professor of Vaccinology, co-author of the study, and the Director of the Vaccines & Infectious Diseases Analytics Research Unit (Wits VIDA), led the Novavax COVID-19 vaccine trial in South Africa.

The published data provide additional detail of an initial analysis conducted in January, while more robust data from a complete analysis of the study was subsequently shared in March 2021.

Publication of initial primary analysis highlights cross-protection by the Novavax COVID-19 vaccine against the B.1.351 variant prevalent in South Africa during the study.

This is the first published study to show protection against mild COVID-19 caused by the B.1.351 variant circulating in South Africa.

An updated analysis of the study indicated 100% protection against severe COVID-19 due to the B.1.351 variant.

"An efficacy of 50% is sufficient to meet the World Health Organization criteria for regulatory approval of the vaccine," says Madhi.

The Novavax COVID-19 vaccine, known as NVX-CoV2373, is made by Novavax, Inc., a US-based biotechnology company developing next-generation vaccines for serious infectious diseases.

Gregory M. Glenn, M.D., president of research and development, Novavax, says: "This data publication reinforces the encouraging safety profile and cross-protective effect across variants seen in studies of our vaccine to-date."

About the study

The Phase 2b randomized, observer-blinded, placebo-controlled trial conducted in South Africa evaluated efficacy, safety and immunogenicity in healthy adults, and in a small cohort of medically stable adults living with human immunodeficiency virus (HIV).

The study met its primary endpoint—i.e., the Novavax vaccine demonstrated an overall efficacy of 49% in the initial analysis (published in *NEJM*), and 49% in the subsequent complete analysis (unpublished).

Among healthy adults without HIV, the Novavax

vaccine demonstrated efficacy of 60% in the initial analysis, and 55% in the subsequent complete analysis.

In the initial analysis, cases were predominantly mild-to-moderate and due to the B.1.351 variant that dominates in South Africa, and increasingly in southern Africa.

In the subsequent complete analysis, circulation of the B.1.351 variant continued to dominate, and all five cases of severe disease observed in the trial occurred in the placebo group.

The initial analysis, now being published in *NEJM*, suggested that prior infection with the original COVID-19 strain did not protect against subsequent infection by the variant predominantly circulating in South Africa through 60 days of follow-up.

However, with additional follow-up, the complete analysis of the South Africa trial indicates that there may be a modest protective effect of prior exposure with the original COVID-19 strain.

Among placebo recipients, at 90 days of follow-up, the illness rate was 8.0% in baseline seronegative participants and 5.9% in baseline seropositive participants.

"The data make a compelling case for use of the Novavax COVID-19 vaccine in settings where the B.1.351 variant dominates—which is most of southern Africa—to reduce the risk of mild disease and also to maximize the opportunity for protection against severe COVID," says Madhi. "Further work is required for Novavax and all other COVID-19 vaccines, particularly in people living with HIV."

The Novavax COVID-19 vaccine trial is one of two COVID-19 vaccine trials in South Africa led by Madhi and Wits VIDA, with the other being the Oxford/AstraZeneca COVID-19 vaccine trial.

In addition to directing Wits VIDA, Madhi is Dean of the Faculty of Health Sciences at the University of the Witwatersrand, Johannesburg (Wits), and co-Director of African Leadership in Vaccinology Expertise (ALIVE).

About the Wits Vaccines & Infectious Diseases Analytics (VIDA) Research Unit

Formerly known as the Respiratory and Meningeal Pathogens Research Unit (RMPRU) and founded in 1995, the Vaccines and Infectious Diseases Analytics (VIDA) Research Unit of the University of the Witwatersrand (Wits) is an internationally recognized, African-led research unit in the field of epidemiology of vaccine preventable diseases, and clinical development of life-saving vaccines.

Under the guidance of Professor Shabir Madhi, a global leader in the field of pediatric infectious diseases and the Dean of the Faculty of Health Sciences at Wits University, Wits VIDA is conducting translational research on vaccine preventable diseases and training the next generation of clinician scientists.

Combining clinical, microbiological and epidemiological expertise in an African setting, Wits VIDA's cutting-edge scientific research informs local and global policy recommendations on the use of next-generation and novel vaccines today.

In addition to various other studies on COVID-19, Wits VIDA championed and led the first two COVID-19 vaccine trials in Africa in 2020, for the Oxford and Novavax vaccine candidates.

About the Novavax vaccine known as NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence of the first strain of SARS-CoV-2, the virus that causes COVID-19 disease.

NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and is with Novavax' patented saponin-based Matrix-M adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19. In pre-clinical studies, NVX-CoV2373

induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease.

It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is stored and stable at two degrees Celsius to eight degrees Celsius, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

More information: Vivek Shinde et al. Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant, *New England Journal of Medicine* (2021). DOI: 10.1056/NEJMoa2103055

Provided by Wits University