

Novavax Statement on PREVENT-19 Phase 3 Clinical Trial Results Publication in the New England Journal of Medicine

December 15, 2021

Today, the full results from PREVENT-19, Novavax' pivotal Phase 3 clinical trial of NVX-CoV2373, a recombinant protein nanoparticle vaccine against COVID-19, were published in the *New England Journal of Medicine*. The paper, '*Efficacy and Safety of NVX-CoV2373 in Adults in the U.S. and Mexico*,' may be accessed [here](#).

PREVENT-19 achieved its endpoint of efficacy in preventing polymerase chain reaction (PCR)-confirmed, symptomatic mild, moderate or severe COVID-19 with onset at least 7 days after the second dose. The trial demonstrated 100% protection against moderate and severe disease, 93.2% efficacy against the predominantly circulating variants of concern and variants of interest, and 90.4% efficacy against COVID-19 of any severity during the time period evaluated. Solicited adverse events were predominantly mild-to-moderate and transient. Severe reactions were infrequent and there were no safety concerns related to vaccination.

PREVENT-19 evaluated the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M™ adjuvant in nearly 30,000 participants 18 years of age and older at 119 locations in the United States and Mexico. The trial included a blinded 'crossover,' ensuring all participants received NVX-CoV2373 without compromising Food and Drug Administration (FDA)-required safety follow-up.

Novavax expects to submit its complete CMC package to FDA for review by the end of 2021.

The manuscript was previously posted to the [medRxiv](#) preprint server in October 2021. [Initial findings](#) from the study were shared in June.