



PRE-fusion Protein Subunit Vaccine Efficacy Novavax Trial | COVID-19



Creating Tomorrow's Vaccines Today

## PREVENT-19: The Novavax Phase 3 Clinical Trial in the U.S. and Mexico

### Evaluating Efficacy, Safety and Immunogenicity of NVX-CoV2373

#### ABOUT NOVAVAX AND PREVENT-19

Novavax, a Maryland-based, late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, has launched PREVENT-19, a Phase 3 trial, being conducted in the United States and Mexico. This study will evaluate the efficacy, safety and immunogenicity of NVX-CoV2373, our vaccine candidate, in preventing COVID-19 disease in adults 18 and older. PREVENT-19 began December 27, 2020.

#### BACKGROUND

PREVENT-19 follows an initial Phase 1/2 trial that showed the vaccine was generally well-tolerated with a reassuring safety profile, across all adult age groups<sup>1</sup>. The vaccine also triggered a robust immune response<sup>1</sup>. Additionally, Novavax is conducting a pivotal Phase 3 study in over 15,000 people in the United Kingdom<sup>2</sup> and is studying vaccine safety and efficacy in a Phase 2b trial in South Africa<sup>3</sup>.

#### NOVAVAX VACCINE DETAILS: A UNIQUE APPROACH

- Our vaccine uses the full-length spike (S) protein of the SARS-CoV-2 virus as the antigen. Antigens are assembled into a nanoparticle complex recognized by the immune system.
- Our adjuvant, Matrix-M™, increases the immune response and has been shown to stimulate high levels of neutralizing antibodies<sup>4</sup>.
- The NVX-CoV2373 protein cannot replicate and cannot cause COVID-19 disease.
- The vaccine is maintained at standard refrigeration conditions (2-8°C).

#### CLINICAL TRIAL DETAILS

PREVENT-19 will enroll about 30,000 adults (18 and older) at approximately 115 locations in the U.S. and Mexico. Participants have a 2-in-3 chance of receiving

#### PREVENT-19 AT A GLANCE

- **Who:** ~30,000 adults 18+ in the U.S. and Mexico
- **Priority:** Older adults (65+) and diverse racial and ethnic populations
- **Approach:** Two-thirds of participants will initially receive active vaccine
- **Focus:** Determine efficacy in prevention of COVID-19 disease

active vaccine (a 1-in-3 chance of receiving a placebo). Enrollment prioritizes populations at high risk for COVID-19, including traditionally under-represented minority groups, people over age 65, and those living with other conditions such as diabetes.

#### OTHER VACCINES

Other COVID-19 vaccines have been granted Emergency Use Authorization (EUA) in the United States. Potential participants should clarify with the study investigator or their healthcare provider whether they are included in the groups recommended to receive the first vaccines under EUA, and how that may impact participation in PREVENT-19.

#### THANK YOU

Novavax is grateful to the thousands of trial participants around the world who are volunteering for our vaccine studies. We thank Operation Warp Speed (OWS) and the Coalition for Epidemic Preparedness Innovations (CEPI) for their significant support of our work.

#### REFERENCES

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