PREVENT-19 Phase 3 Trial Data Factsheet

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

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On December 27, 2020, Novavax launched PREVENT-19, a Phase 3 study of its NVX-CoV2373 vaccine in the US and Mexico. PREVENT-19 is a randomized, observer-blinded, placebo-controlled trial evaluating vaccine efficacy, immunogenicity, and safety in adults 18 and older.

Results of PREVENT-19 follow a successful Phase 3 (United Kingdom) study that showed the vaccine to be well-tolerated with high levels of efficacy against original and variant virus strains[1] and a successful Phase 2b study in South Africa[2].

PREVENT-19 Highlights

90.4% overall efficacy (primary endpoint)

100% protection against moderate & severe disease

93.2% efficacy against Variants of Interest/Concern

91% efficacy in "high-risk" populations

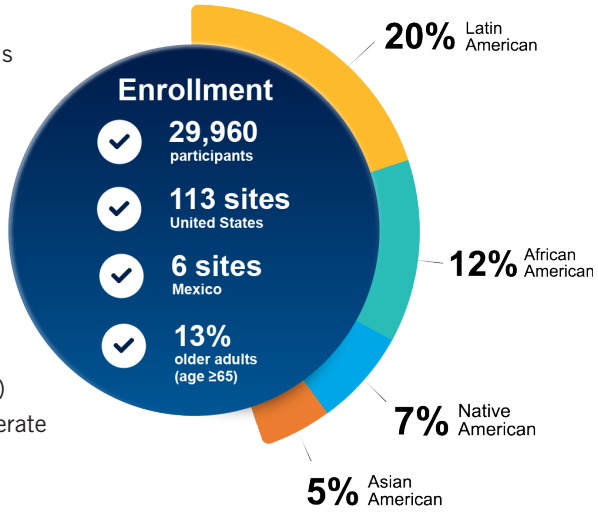
Two doses of NVX-CoV2373 vaccine are well-tolerated and show high levels of efficacy

NVX-CoV2373 VACCINE

- Vaccine platform: Recombinant protein nanoparticle vaccine
- Antigen: 5µg of full-length spike (S) protein of the prototype SARS-CoV-2 virus
- Adjuvant: 50µg of Matrix-M™ adjuvant
- Administration: 2 doses, 21 days apart
- Premixed and stable at standard refrigeration conditions (2-8°C)

STUDY DETAILS

- 119 total sites: 113 in the US and 6 in Mexico
- 2:1 randomization of active vaccine to placebo groups
- Enrollment priority: traditionally under-represented minority groups and populations at high risk for COVID-19 (over age 65, under age 65 with comorbidities, or having life circumstances with frequent COVID-19 exposure)
- Primary Endpoint: The development of PCR-positive, symptomatic mild, moderate or severe COVID-19 illness diagnosed 7 days after the second vaccine dose
- Timing: Dose 1: December 27, 2020 – February 18, 2021
  Dose 2: January 18, 2021 – March 26, 2021
- Efficacy Endpoint Accrual: January 25, 2021 – April 30, 2021



CLINICAL TRIAL RESULTS

High Levels of Efficacy

Overall: Vaccine efficacy = **90.4%** (95% CI: 82.9, 94.6)

- 77 cases: 63 in the placebo group, 14 in the vaccine group
- All cases in the vaccine group were mild
- Met the primary endpoint success criteria

Moderate or severe disease: Vaccine efficacy = **100%** (95% CI: 87, 100)

- 10 moderate cases and 4 severe cases, all in the placebo group

"High-risk" populations: Vaccine efficacy = **91.0%** (95% CI: 83.6, 95.0)

- 62 COVID-19 cases in the placebo group, 13 COVID-19 cases in the vaccine group

High levels of efficacy against variants; see next page for details

	FINAL ANALYSIS	
	NVX-CoV2373 n=17,315	**Placebo** n=8,142
Total	14	63
Mild	14	49
Moderate	0	10
Severe	0	4
Vaccine Efficacy	90.4% (95% CI: 82.9, 94.6)	

Table 1. Final analysis of PREVENT-19 Phase 3 Trial.

THANK YOU

Novavax is grateful to the thousands of clinical trial participants around the world who are volunteering in our vaccine studies. We thank the United States Government and the NIH/NIAID Data Safety Monitoring Board for their support of this Phase 3 trial, along with the United Kingdom Vaccine Task Force (VTF) and Coalition for Epidemic Preparedness Innovations (CEPI) for their overall support.

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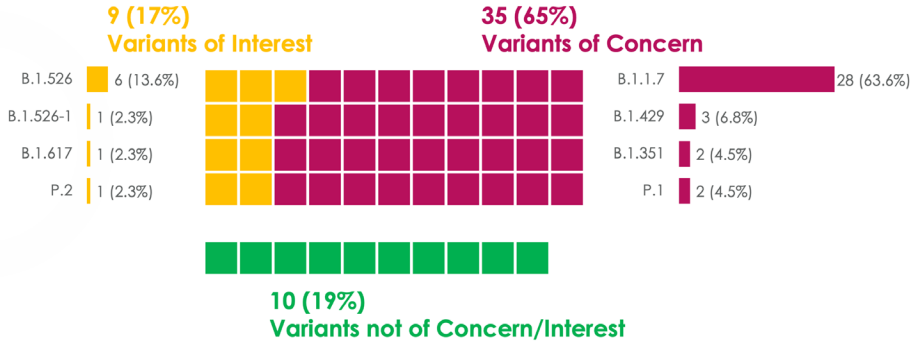
High Efficacy Against Variants

- Sequencing for 54 of 77 cases (Figure 1):
  - 35 (65%) = Variants of Concern (VoC)
  - 9 (17%) = Variants of Interest (VoI)
  - 10 (19%) = variants not considered VoC/VoI
- Click here for CDC definitions of variants



Variants not considered VoC/VoI:

Vaccine efficacy = **100%** (95% CI: 80.8, 100)

VoC/VoI:

Vaccine efficacy = **93.2%** (95% CI: 83.9, 97.1)

- 38 of the VoC/VoI cases were in the placebo group, 6 were in the vaccine group

Favorable Safety Profile

- Preliminary safety data: generally **well-tolerated** (Figure 2)
- Serious and severe adverse events: **low in number, balanced between vaccine and placebo groups** (Figure 3)
- No single adverse event term was reported by more than 1% of participants
- Includes evaluation in a **highly diverse and at-risk study population**

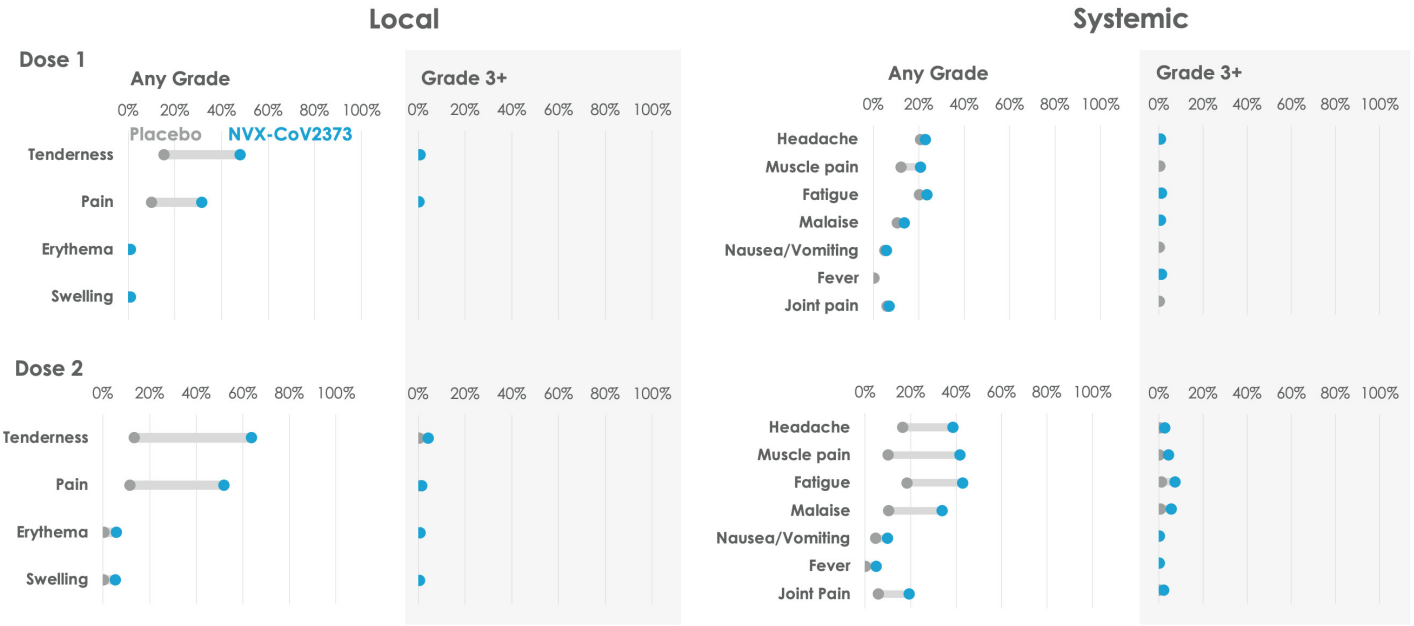


Figure 2. Local and systemic reactogenicity of NVX-CoV2373 for the PREVENT-19 trial, showing the vaccine to be generally well-tolerated.

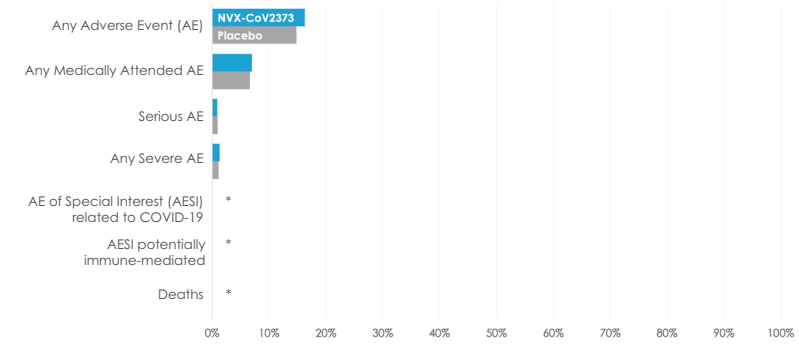


Figure 3. Unsolicited adverse events observed in PREVENT-19 were low in number and balanced between vaccine and placebo groups. *Rates less than 0.08%.

NEXT STEPS

Novavax expects to share further details of PREVENT-19 as additional data become available. The placebo-controlled portion of PREVENT-19 continues in adolescents from 12 to less than 18 years of age, which recently completed enrollment of 2,248 participants. For more information, please visit novavax.com.

REFERENCES

1. Heath, P.T. et al. www.medrxiv.org/content/10.1101/2021.05.13.21256639v1
2. Shinde, V. et al. www.nejm.org/doi/full/10.1056/NEJMoa2103055