

Announcement of UK and South Africa Trial Results

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### Safe Harbor

Statement

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#### **Breaking News**

Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial

### First to Demonstrate Clinical Efficacy Against COVID-19 and Both UK and South Africa Variants

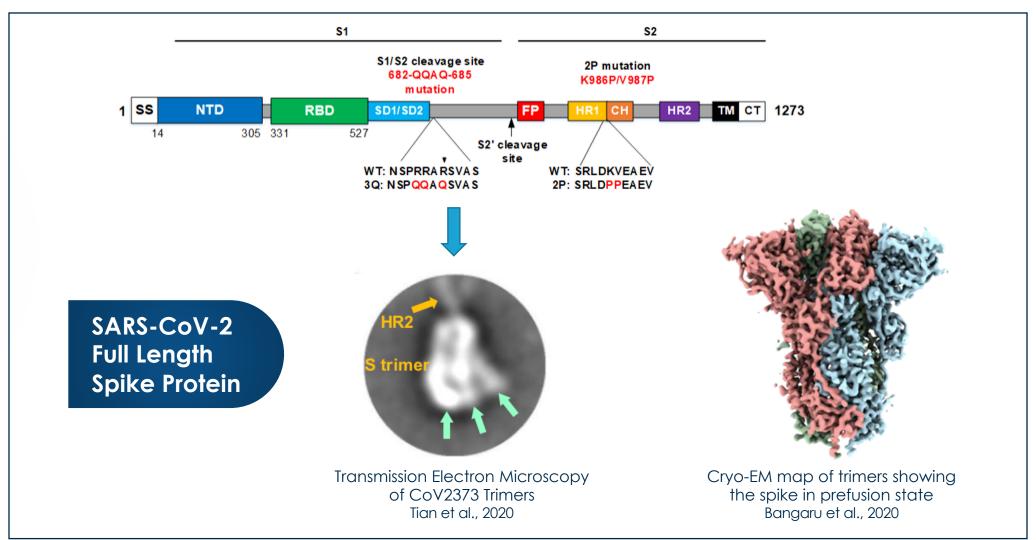
- Strong efficacy in Phase 3 UK trial with over 50% of cases attributable to the now-predominant UK variant and the remainder attributable to COVID-19 virus
- Clinical efficacy demonstrated in Phase 2b South Africa trial with over 90% of sequenced cases attributable to prevalent South Africa escape variant



#### Agenda

- Results from Phase 3 Trial in United Kingdom
- Results from Phase 2b Trial in South Africa
- Update on PREVENT-19 Phase 3 Trial in the US and Mexico
- Next Steps

# NVX-CoV2373: A full-length, prefusion stabilized SARS-CoV-2 spike (S) glycoprotein + Matrix-M™





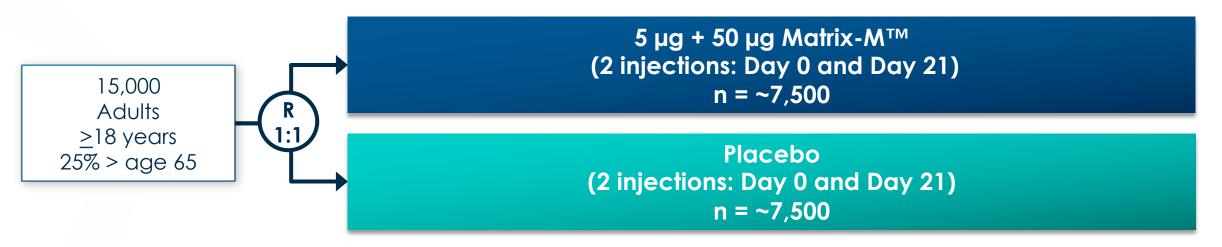
NVX-CoV2373 UK Phase 3 Study





#### **UK Phase 3 Study Design**

Randomized, observer-blinded, placebo-controlled trial evaluating efficacy, immunogenicity and safety



 Primary endpoint: PCR-positive symptomatic mild, moderate or severe COVID-19 illness diagnosed ≥ 7 days after second dose



# UK 501Y.V1 Mutant Strain Increased in Prevalence During Efficacy Collection Window

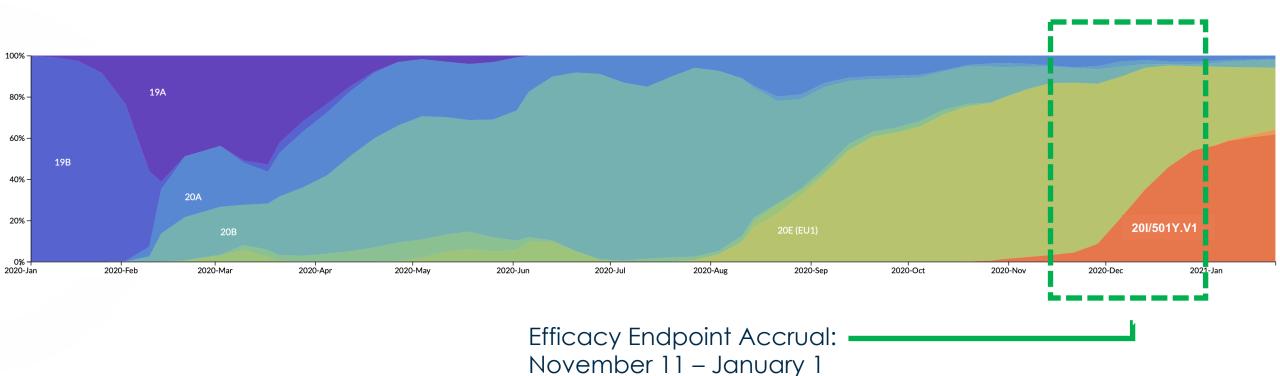


Figure Source: Nextstrain.org





### Primary Endpoint Met in Interim Analysis

Severity	NVX-CoV2373 (n=7,016)	Placebo (n=7,033)	
Total	6	56	
Mild	1	15	
Moderate	5	40	
Severe	0	1	
Vaccine Efficacy	<b>89.3%</b> (95% CI: 75.2, 95.4)		

- Preliminary PCR data show >50% of cases attributable to UK 501Y.V1 variant
- Final analysis to be conducted once at least 100 cases accrued

Primary Endpoint: PCR-confirmed mild, moderate, or severe COVID-19 illness occurring ≥7 days after second dose in baseline seronegative participants



### Summary of PCR-Confirmed Mild, Moderate or Severe COVID-19 with Onset from 7 Days after the Second Vaccination by Variant Strain and Severity, Per-Protocol Efficacy Analysis Set

	SARS-CoV-2 rS (5 μg) + Matrix-M1 adjuvant (50 μg) (N=7016)		Placebo (N=7033)			
	Variant- UK	Non- Variant	No Sequence Data	Variant- UK	Non- Variant	No Sequence Data
PCR-Confirmed COVID-19 Symptomatic Mild, Moderate, Severe	4	1	1	28	23	5

Preliminary, post-hoc analysis based on PCR performed on strains from 56 of the 62 cases showed **96%** efficacy in the COVID-19 strain, **86%** efficacy in the variant strain.



### Favorable Preliminary Safety Profile

Event	NVX-CoV2373 (n=7,016)	Placebo (n=7,033)
Any Severe TEAE	81 (1.1 %)	53 (0.7%)
Any Serious TEAE	31 (0.4%)	30 (0.4%)
Any MAAE	202 (2.7%)	201 (2.8%)



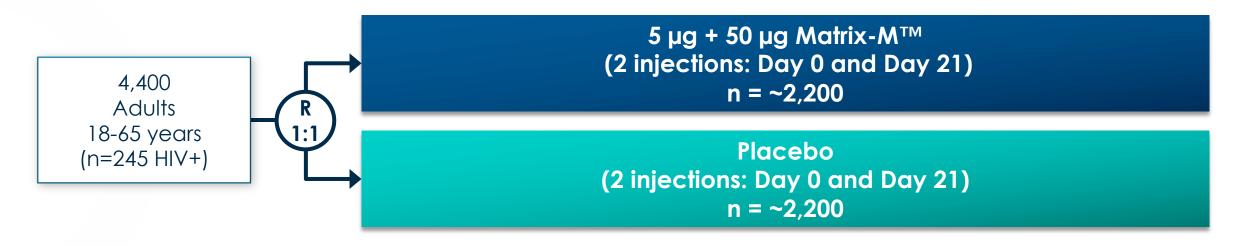
NVX-CoV2373 South Africa Phase 2b Study





### South Africa Phase 2b Study Design

Randomized, observer-blinded, placebo-controlled trial evaluating efficacy, immunogenicity and safety



- Enrollment population includes cohort of 245 randomized participants who are HIV-positive
- Efficacy analysis at 23 50 events



# South Africa 501Y.V2 Escape Mutant Dominant During Efficacy Collection Window

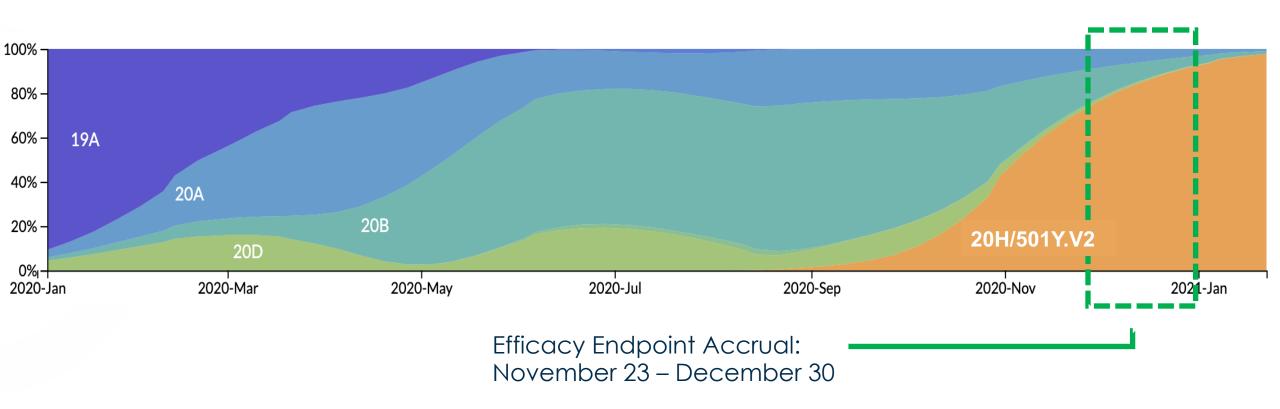


Figure Source: Nextstrain.org





### Cross-Protection Demonstrated Against South Africa Escape Variant

Severity	NVX-CoV2373 (n=2,206)	Placebo (n=2,200)
Total	15	29
Vaccine Efficacy (HIV negative)	<b>60.1 %</b> (95% CI: 19.9, 80.1)	
Vaccine Efficacy (overall)	<b>49.4%</b> (95% CI: 6.1, 72.8)	

• Sequencing data show 25/27 (93%) of cases attributable to SA 501Y.V2 escape variant

Primary Endpoint: PCR-confirmed mild, moderate, or severe COVID-19 illness occurring ≥7 days after second dose in baseline seronegative participants





## Prior COVID-19 Infection with Original Strain May Not Provide Protection Against South Africa 501Y.V2 Escape Variant

- Nearly 1/3 of study participants had prior COVID-19 infection
- COVID-19 case rate in placebo group not impacted by baseline anti-spike serostatus
- NVX-CoV2373 first vaccine with clinical data on protection against 501Y.V2 escape variant



### Booster / Bivalent Vaccine Development

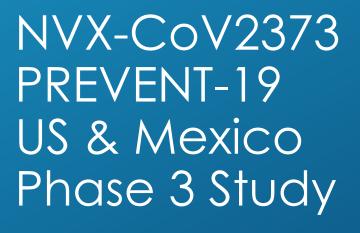
# Variant Strains Already Under Development Against Emerging COVID-19 Mutations

- To address an evolving pandemic, the optimal vaccine for all regions may need to contain multiple strains
- Lab-scale manufacturing underway for multiple strains
- Will be able to rapidly scale up production of additional recombinant protein vaccine candidates

Expect clinical testing to start in Q2



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



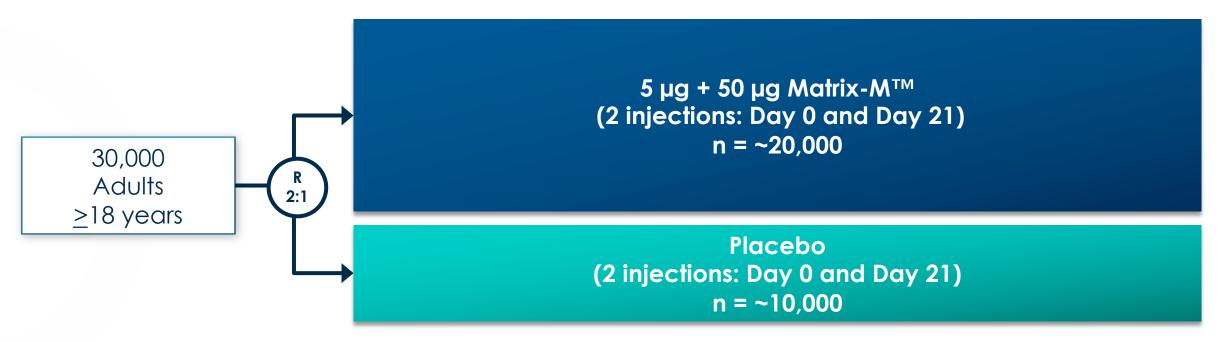




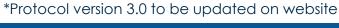


#### PREVENT-19 Phase 3 Trial Currently Enrolling

Randomized, observer-blinded, placebo-controlled trial evaluating efficacy, immunogenicity and safety



- Primary endpoint: PCR-positive symptomatic mild, moderate or severe COVID-19 illness diagnosed ≥ 7 days after second dose
- Interim analysis at 72 events, final analysis at 144 events\*









### PREVENT-19 Phase 3 Enrollment Update

Characteristic	Current Status
Total Randomized - as of 1/27/21	16,748
≥ 65 Years	17%
Black/African American	13%
LatinX	14%

- Enrollment expected to complete first half of February
- Drop-out rate: 1% overall; 2% among ≥ 65 years
- Protocol amended to incorporate blinded crossover

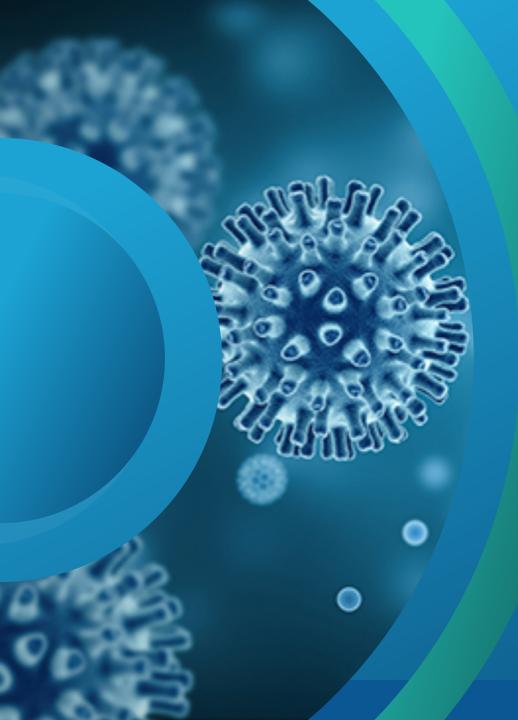


### Regulatory Update

#### Regulatory Updates

Initiated rolling submission in UK

 Actively working in collaboration with global regulatory authorities to determine pathway and timing of EUA



### Summary

# Two Independent Trials Demonstrate Statistically Significant Efficacy of NVX-CoV-2373

- First clinical vaccine data on UK and South Africa COVID-19 variant strains
- Preliminary results from 2 independent efficacy studies demonstrate statistically significant efficacy
  - Cross-protection demonstrated against UK and SA variant strains
  - Prior COVID-19 infection may not completely protect against infection with South Africa 501Y.V2 escape variant
- Variant vaccines already under development against emerging COVID-19 strains
  - Clinical testing expected in Q2 2021

#### **Thank You**

- Trial participants
- Clinical research staff
- Vaccine Task Force in UK
- Dr. Shabir Maddi and Wits University
- Partners in South Africa
- The Bill and Melinda Gates Foundation
- CEPI
- US government



