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Creating Tomorrow's Vaccines Today

NAIIS – Developing COVID-19 Vaccines in Record Time

Nasdaq: NVAX | January 29, 2021

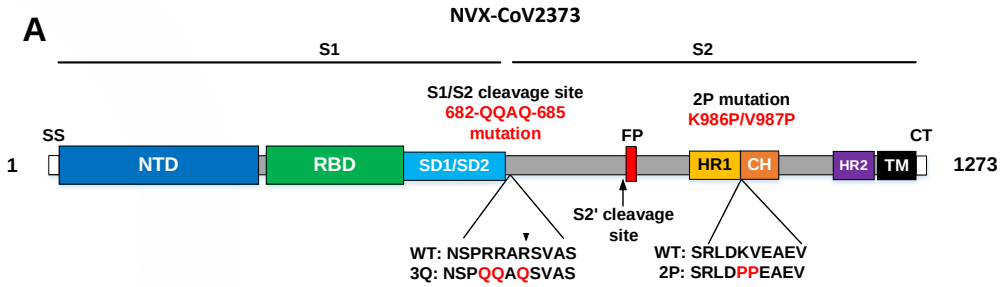
NVX-CoV2373 Vaccine Design

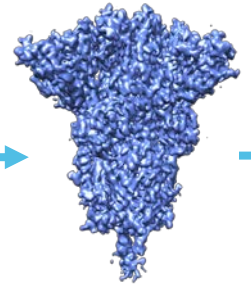
Vaccine Platform Technology: Nanoparticle vaccine formulated with Matrix-M1

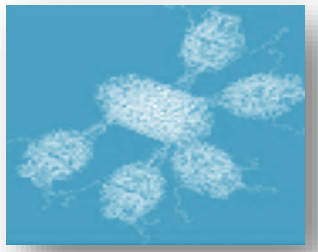
Antigen expressed in baculovirus-*S. frugiperda* system
- Codon-optimized
- Full-length protein, including transmembrane domain
- Furin cleavage site mutated and stabilized

Drug Substance
- Native conformation trimers
- Stable PS80 nanoparticle

Drug Product
- Co-formulated with adjuvant
- Dispensed in vial
- Stored 2-8^{O} C

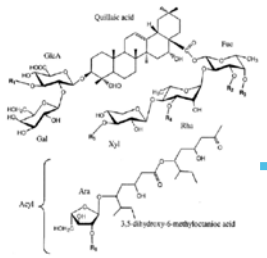


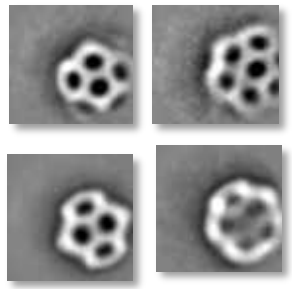


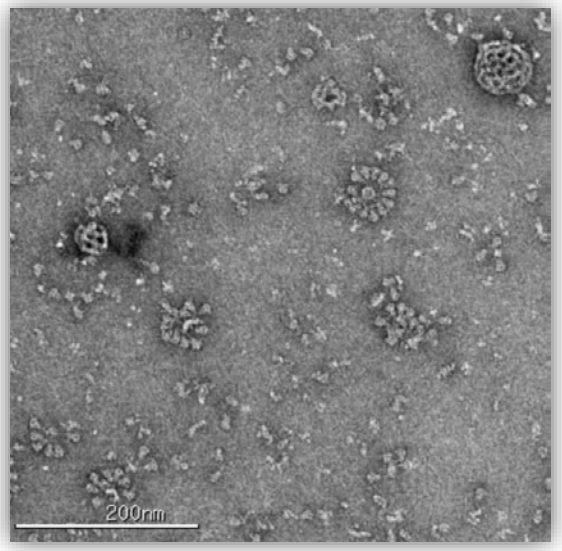


Matrix-M adjuvant
- Purified from *Quillaja saponaria molina*

Matrix-M Adjuvant



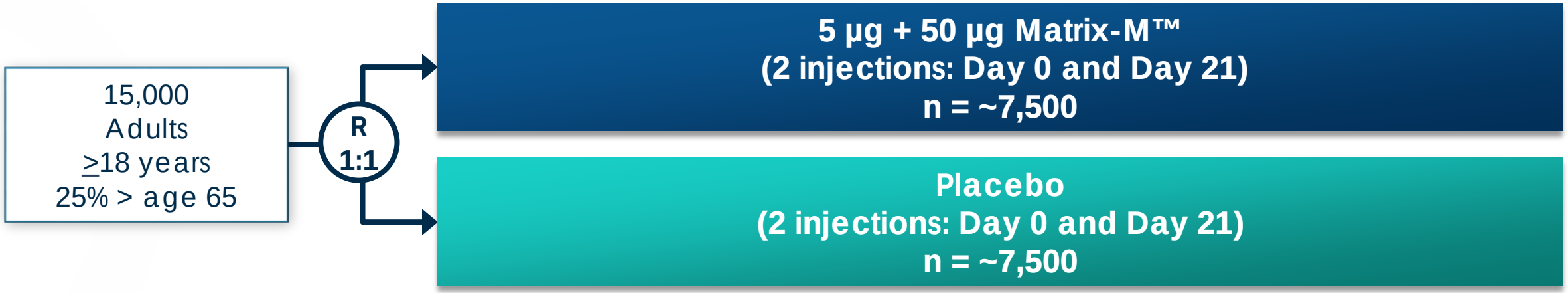




Bangaru et al. bioRxiv 06 August 2020 and Tian et al. bioRxiv 30 June 2020

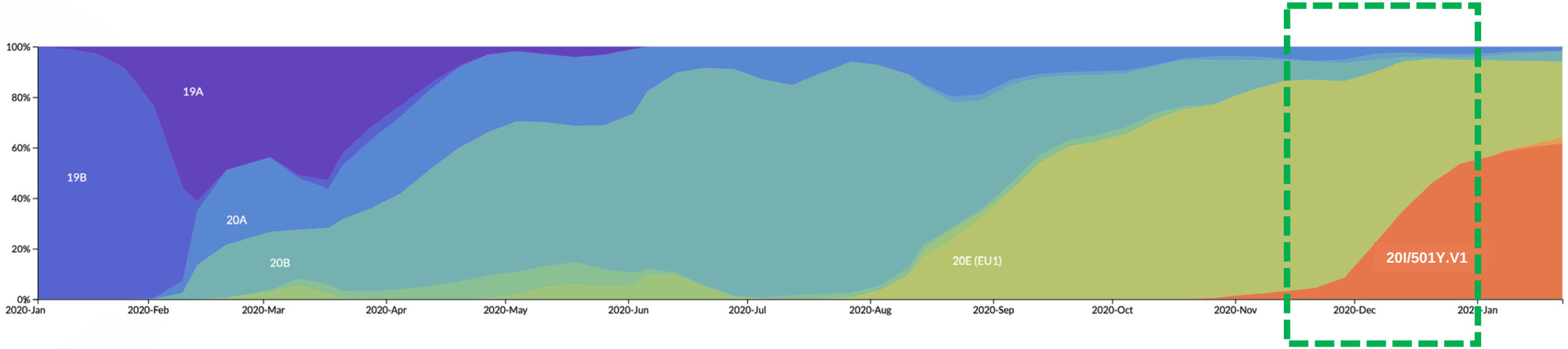
UK Phase 3 Study Design

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
- LBCI >30 success criteria

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



Efficacy Endpoint Accrual:
November 11 – January 1

Figure Source: Nextstrain.org

Primary Endpoint Met

Severity	NVX-CoV2373 (n=7,016)	Placebo (n=7,033)
Total	**6**	**56**
Mild	*1*	*15*
Moderate	*5*	*40*
Severe	*0*	*1*
Vaccine Efficacy	**89.3%** (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

PCR-Confirmed Mild, Moderate or Severe COVID-19

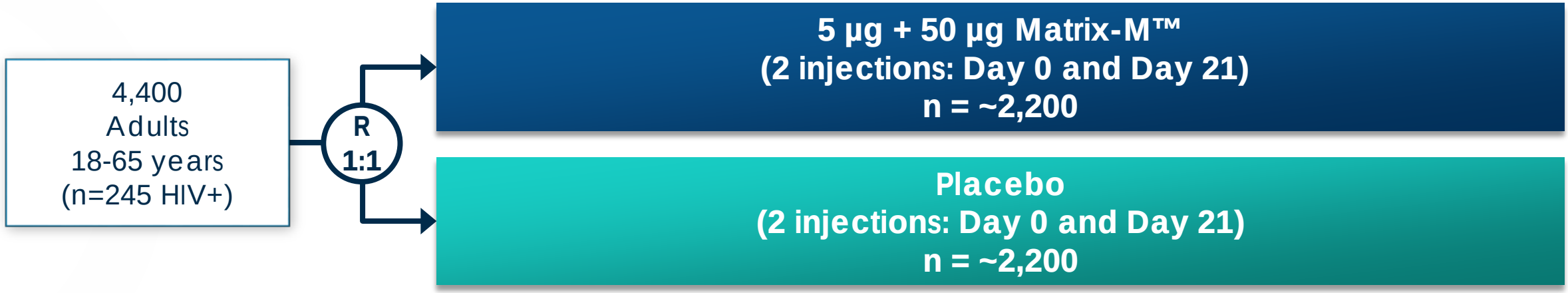
by Strain (Original vs 501Y.V1 Variant)

	NVX-CoV2373 (n=7016)			Placebo (n=7033)		
	501Y.V1	Original	Unknown	501Y.V1	Original	Unknown
PCR-Confirmed COVID-19 (Mild, Moderate, Severe)	4	1	1	28	23	5
Mild	1	0	0	5	7	3
Moderate	3	1	1	22	16	2
Severe	0	0	0	1	0	0

Preliminary, post-hoc analysis based on PCR performed on strains from 56 of the 62 cases showed **96/94%** PP/Moderate-Severe efficacy in the original COVID-19 strain, **86/87%** efficacy in the 501Y.V1 variant strain.

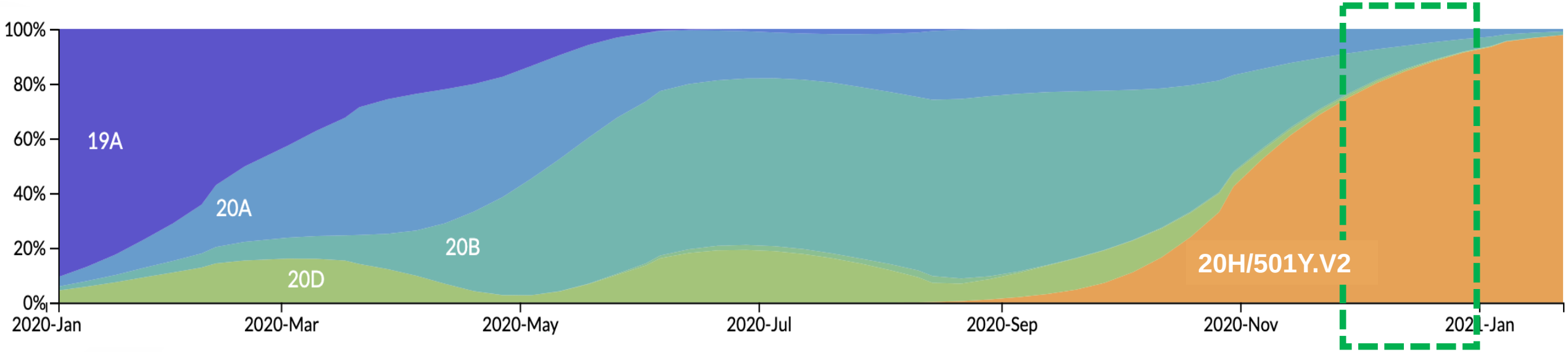
South Africa Phase 2b Study Design

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, LBCI success at 0.
- Primary endpoint: PCR-positive symptomatic mild, moderate or severe COVID-19 illness diagnosed ≥ 7 days after second dose

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



Efficacy Endpoint Accrual:
November 23 – December 30

Figure Source: Nextstrain.org

Attack Rate In Placebo Groups By Serostatus

No Evidence Of Resistance From Infection With Previous COVID Exposure

- Placebo Per-protocol population time frame (7 days post-dose 2)
  - Seronegative: 29/1327 2.185% (1.468; 3.124)
  - Seropositive: 13/514 2.529% (1.353; 4.286)

- Placebo ITT population (7 days post-dose 1)
  - Seronegative: 58/1494 3.882% (2.961; 4.990)
  - Seropositive : 26/674 3.858% (2.535; 5.601)

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)	**60.1 %** (95% CI: 19.9, 80.1)	
Vaccine Efficacy (overall)	**49.4%** (95% CI: 6.1, 72.8)	

- Preliminary PCR 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

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

- Overall UK Phase 3 Vaccine Efficacy = **89.3%**
  - Original/Strain matched VE = **96%**
  - UK Variant 501Y.V1 VE = **86%**
- ZA Phase 2b Vaccine Efficacy = **60%**
  - Prior COVID-19 infection **does not** appear to protect against infection with 501Y.V2 variant
  - Conversely, NVX-CoV2373 **achieved protection**
- Developing 501Y.V2 variant, **multiple candidates**
  - 501Y.V2 rS vaccine candidate has been produced at lab-scale for testing

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THANK YOU