

The background is a dark blue gradient with several concentric circles in lighter shades of blue. A faint, stylized image of a coronavirus particle is visible in the center. The Novavax logo is prominently displayed in the upper left quadrant.

# **NOVAVAX**

Creating Tomorrow's Vaccines Today

## **NVX-CoV2373 COVID-19 Vaccine Candidate Phase 1/2, Part 1, Clinical Trial Results**

Nasdaq: NVAX | August 4, 2020

# Safe Harbor Statement

Certain information, particularly information relating to future performance and other business matters, including expectations regarding clinical development, our planned use of the proceeds from the offering, market opportunities and anticipated milestones constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act.

Forward-looking statements may generally contain words such as “believe,” “may,” “could,” “will,” “possible,” “can,” “estimate,” “continue,” “ongoing,” “consider,” “intend,” “indicate,” “plan,” “project,” “expect,” “should,” “would,” or “assume” or variations of such words or other words with similar meanings. Novavax cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time and may cause actual results to differ materially from the results discussed in the forward-looking statements.

Uncertainties include but are not limited to clinical trial results, dependence on third party contractors, competition for clinical resources and patient enrollment and risks that we may lack the financial resources to fund ongoing operations.

Additional information on Risk Factors are contained in Novavax’ filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2019, our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K, which are all available at <http://www.sec.gov>.

Forward-looking statements are based on current expectations and assumptions and currently available data and are neither predictions nor guarantees of future events or performance.

Current results may not be predictive of future results.

You should not place undue reliance on forward-looking statements which speak only as of the date hereof.

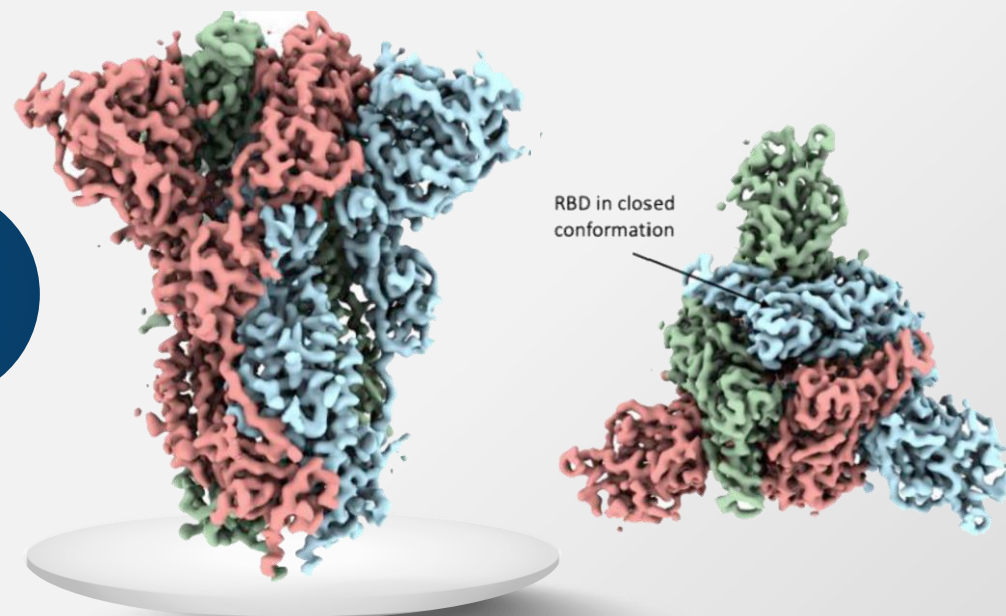
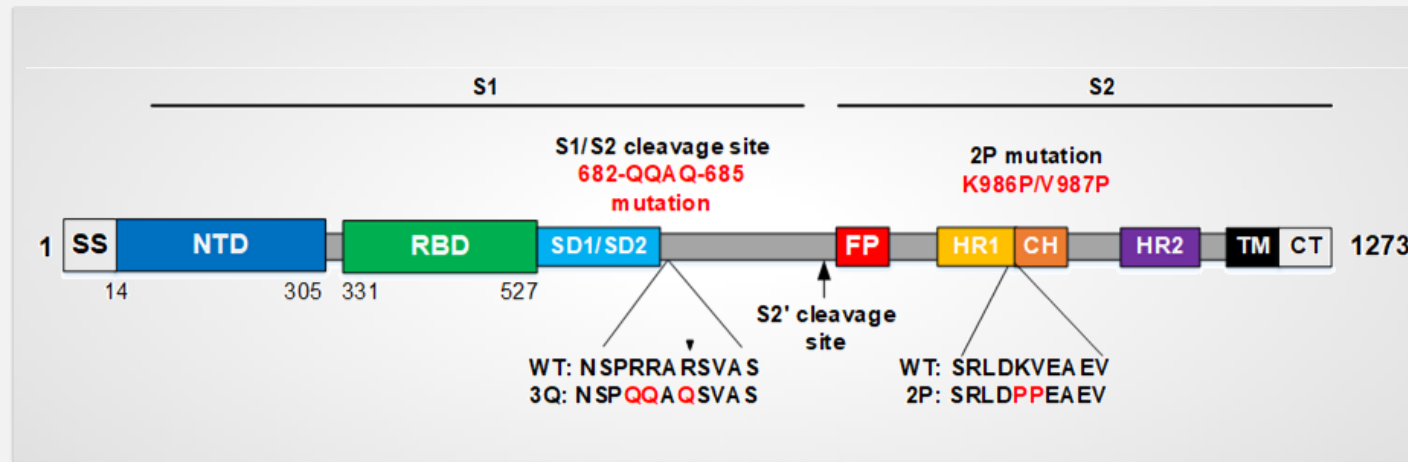
The Company does not undertake to update or revise any forward-looking statements after they are made, whether as a result of new information, future events, or otherwise, except as required by applicable law.

Matrix-M and NanoFlu are trademarks of Novavax, Inc.

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

- Full-length native confirmation trimer nanoparticle formulated with Matrix-M
- Liquid formulation in vials, stable at 2°C to 8°C

### SARS-CoV-2 Protein Spike

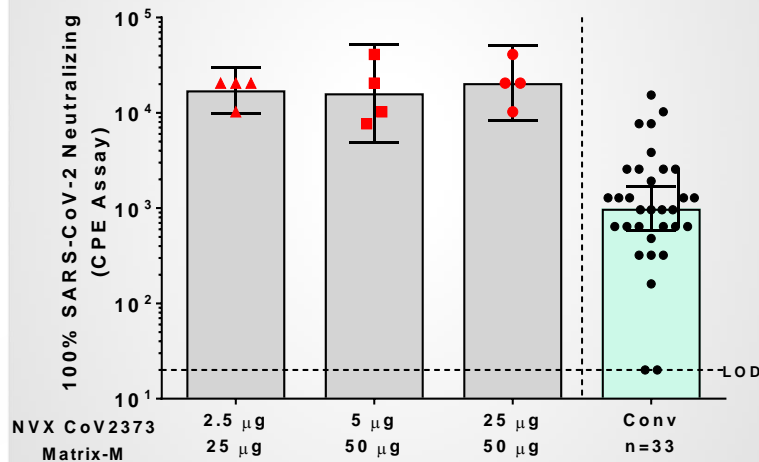


Bangaru S. et al, bioRxiv, August 2020; Tian et al., bioRxiv, July 2020

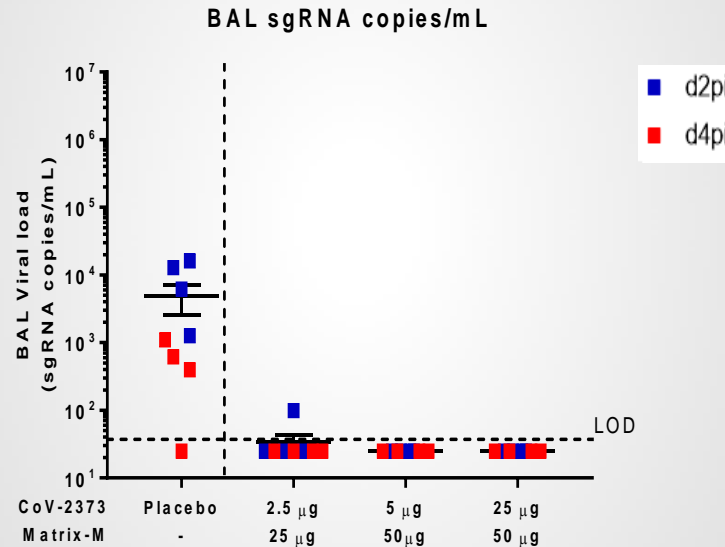
# NVX-CoV2373 in cynomolgus macaques

Induced sterile immunity that prevented viral replication in the upper and lower respiratory tracts in experimentally challenged macaques

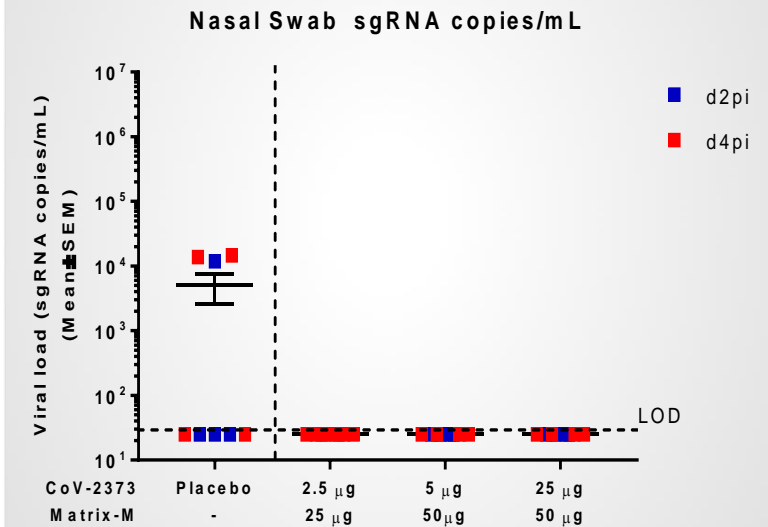
## 100% wild-type neutralization



## Lower airway protection



## Upper airway protection



Doses administered on Day 0, 21 and challenged with  $10\log_4$  IT/IN on Day 37



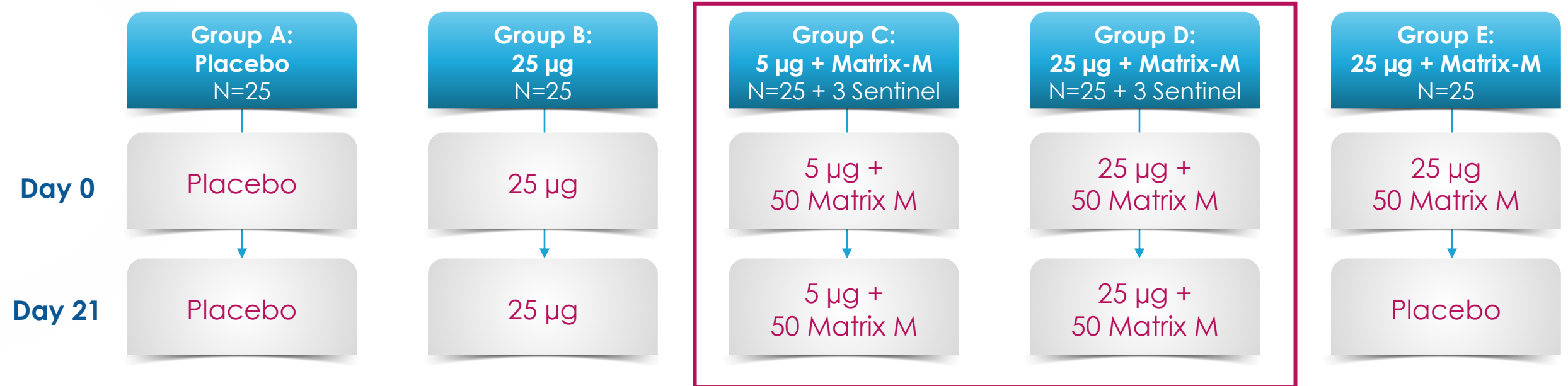


# Phase 1/2 Part 1

# Phase 1/2, part 1 randomized, observer-blinded, placebo-controlled designed to evaluate the immunogenicity and safety of NVX-CoV2373

Trial regimen assesses 5 and 25 µg dose levels with and without Matrix M Adjuvant

Australia — N=131 | Adults ages 18-59 years



Development goal:

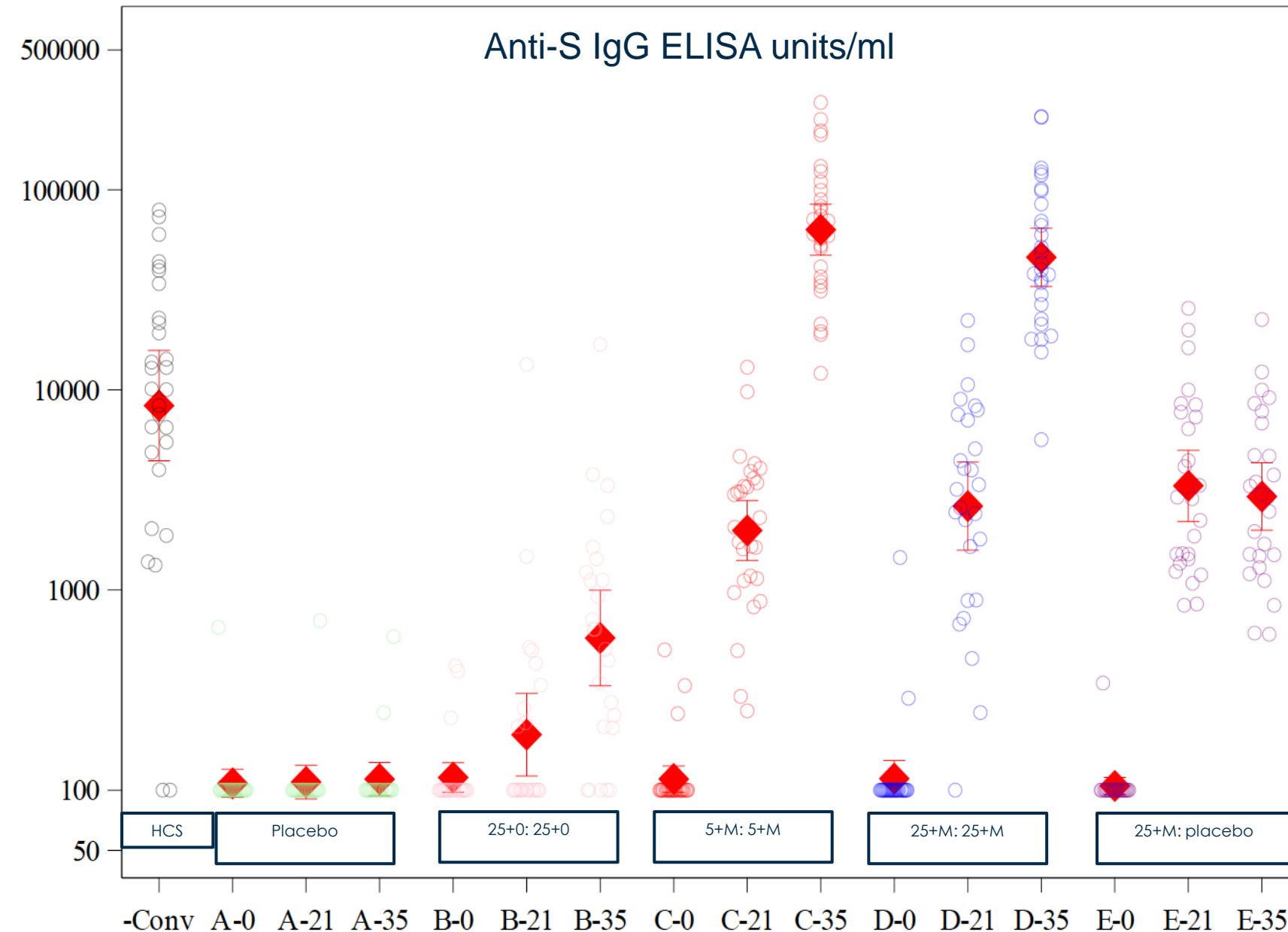
- FTiH safety
- Dose-selection and demonstration of adjuvant utility

# Study objectives

**Phase 1 trial  
evaluated the safety  
and immunogenicity  
of NVX-CoV2373  
with or without  
Matrix M adjuvant**

1. Primary outcomes were reactogenicity, safety laboratory assessments, and immunoglobulin G (IgG) anti-spike protein response
2. Secondary outcomes included adverse events, wild-type neutralizing antibodies, and T cell responses

## Anti-S IgG ELISA units/ml



**2 doses of vaccine induces high levels of IgG**

### Covid-19 Convalescent Sera (Baylor)

GMEU 8,344 (95% CI 4,420; 15,747)

#### A: Placebo

Day 35 GMEU 114 (95% CI: 94; 138)

#### B: 2 dose 25 ug (no adjuvant)

Day 35 GMEU 576 (95% CI: 332; 999)

#### C: 2 doses 5 ug + Matrix-M

Day 35 GMEU 63,160 (95% CI: 47,117; 84,666)

#### D: 2 doses 25 ug + Matrix-M

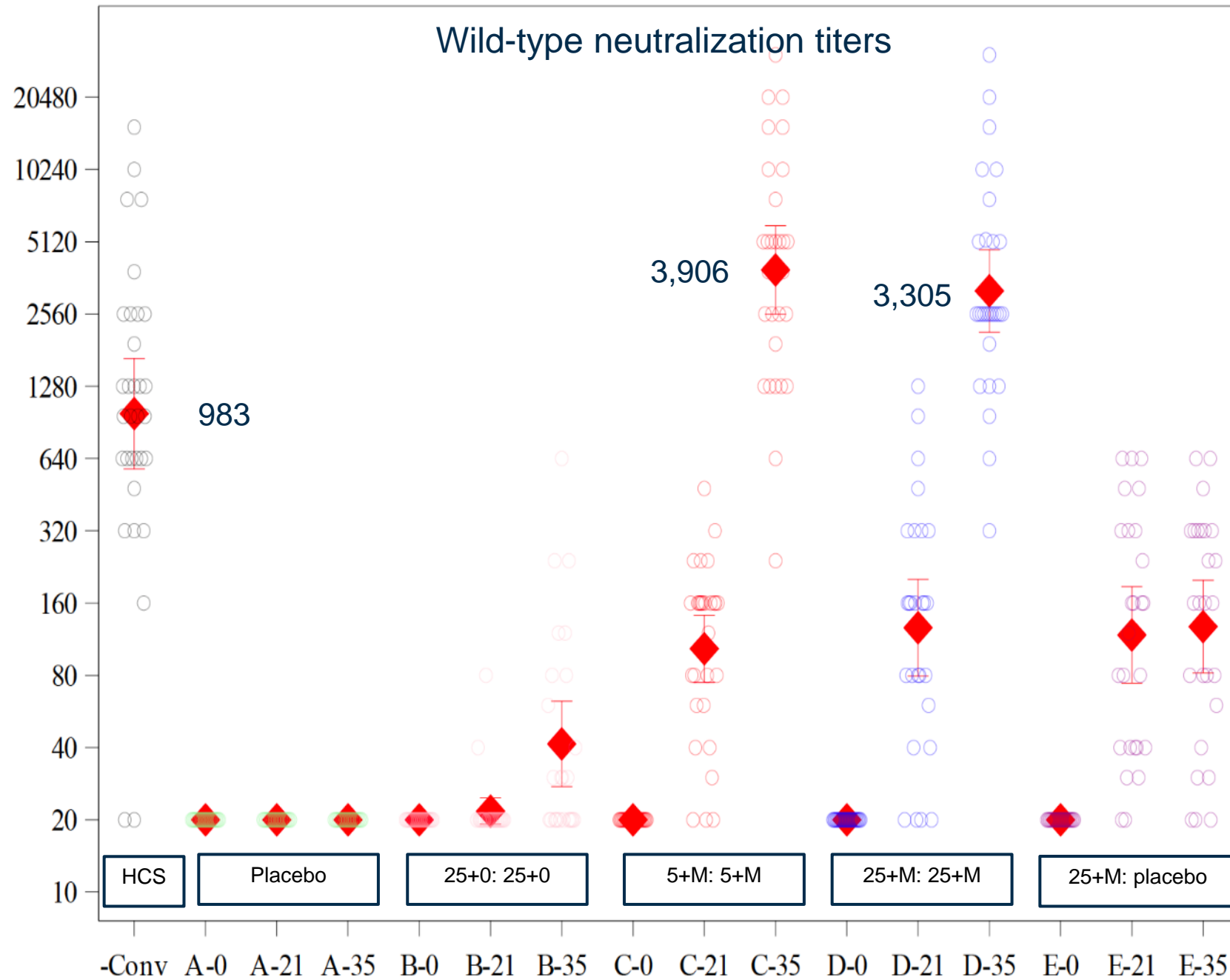
Day 35 GMEU 47,521 (95% CI: 33,803; 66,804)

#### E: 1 dose 25 ug + Matrix-M

Day 35 GMEU 2,932 (95% CI: 1,988; 4,325)



## Wild-type neutralization titers



**100% of participants developed neutralizing responses with 2 doses of the vaccine**

### Covid-19 Convalescent Sera (Baylor)

GMT 983 (95% CI 579; 1,670)

#### A: Placebo

Day 35 GMT 20 (95% CI: 20; 20)

#### B: 2 dose 25 ug (no adjuvant)

Day 35 GMT 41 (95% CI: 28; 62)

#### C: 2 doses 5 ug + Matrix-M

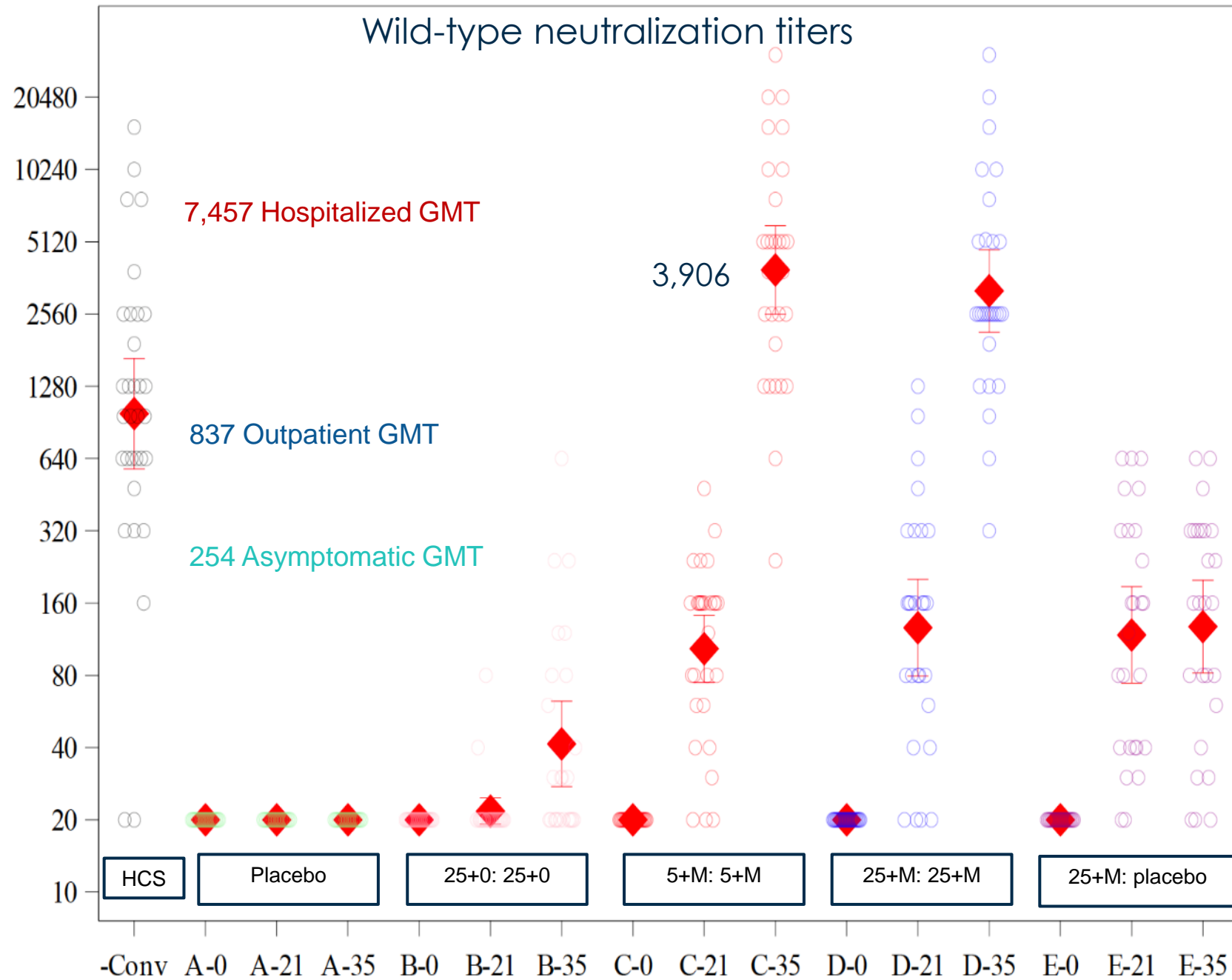
Day 35 GMT 3,906 (95% CI: 2,556; 5,970)

#### D: 2 doses 25 ug + Matrix-M

Day 35 GMT 3,305 (95% CI: 2,205; 4,953)

#### E: 1 dose 25 ug + Matrix-M

Day 35 GMT 128 (95% CI: 82; 199)



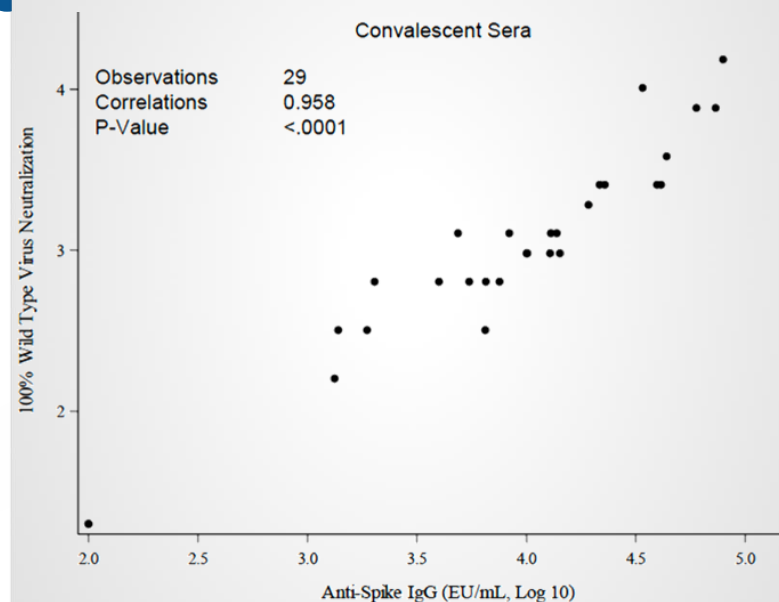
## Vaccine responses compared favorably with HCS in patients with clinically significant disease

<b>Covid-19 Convalescent Sera (Baylor)</b>	
GMT	983 (95% CI 579; 1,670)
<b>A: Placebo</b>	
Day 35 GMT	20 (95% CI: 20; 20)
<b>B: 2 dose 25 ug (no adjuvant)</b>	
Day 35 GMT	41 (95% CI: 28; 62)
<b>C: 2 doses 5 ug + Matrix-M</b>	
Day 35 GMT	3,906 (95% CI: 2,556; 5,970)
<b>D: 2 doses 25 ug + Matrix-M</b>	
Day 35 GMT	3,305 (95% CI: 2,205; 4,953)
<b>E: 1 dose 25 ug + Matrix-M</b>	
Day 35 GMT	128 (95% CI: 82; 199)

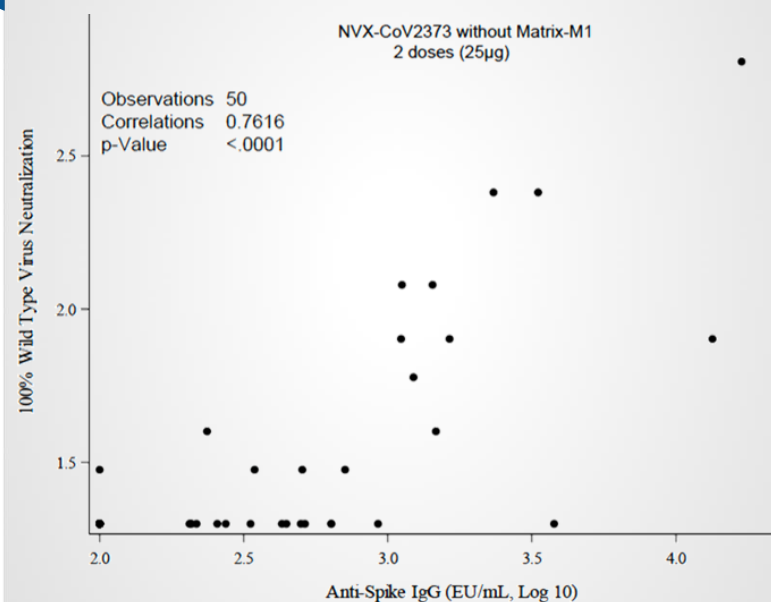
# Scatter plot of IgG vs wild-type neutralization

Adjuvanted vaccine IgG response correlates tightly with neutralization response  
Demonstrating that a significant portion of antibody is functional

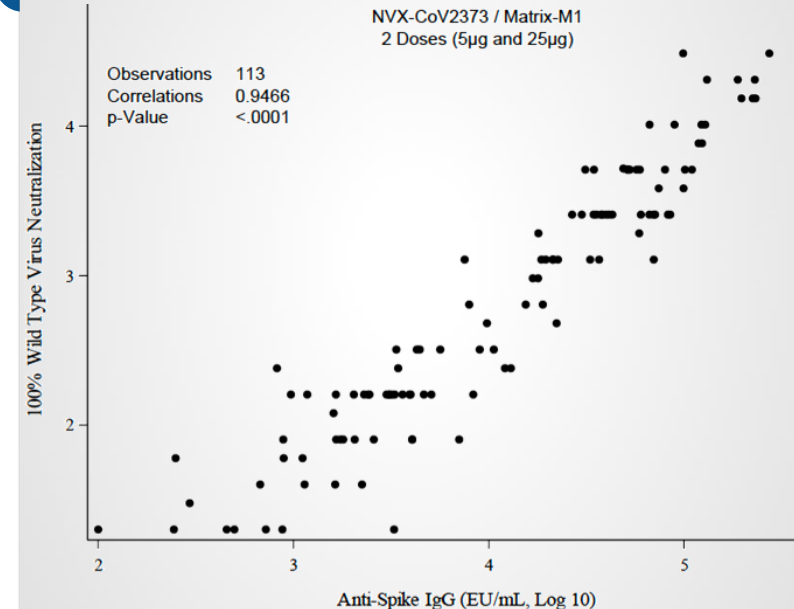
Convalescent serum



Antigen alone dose group (B)

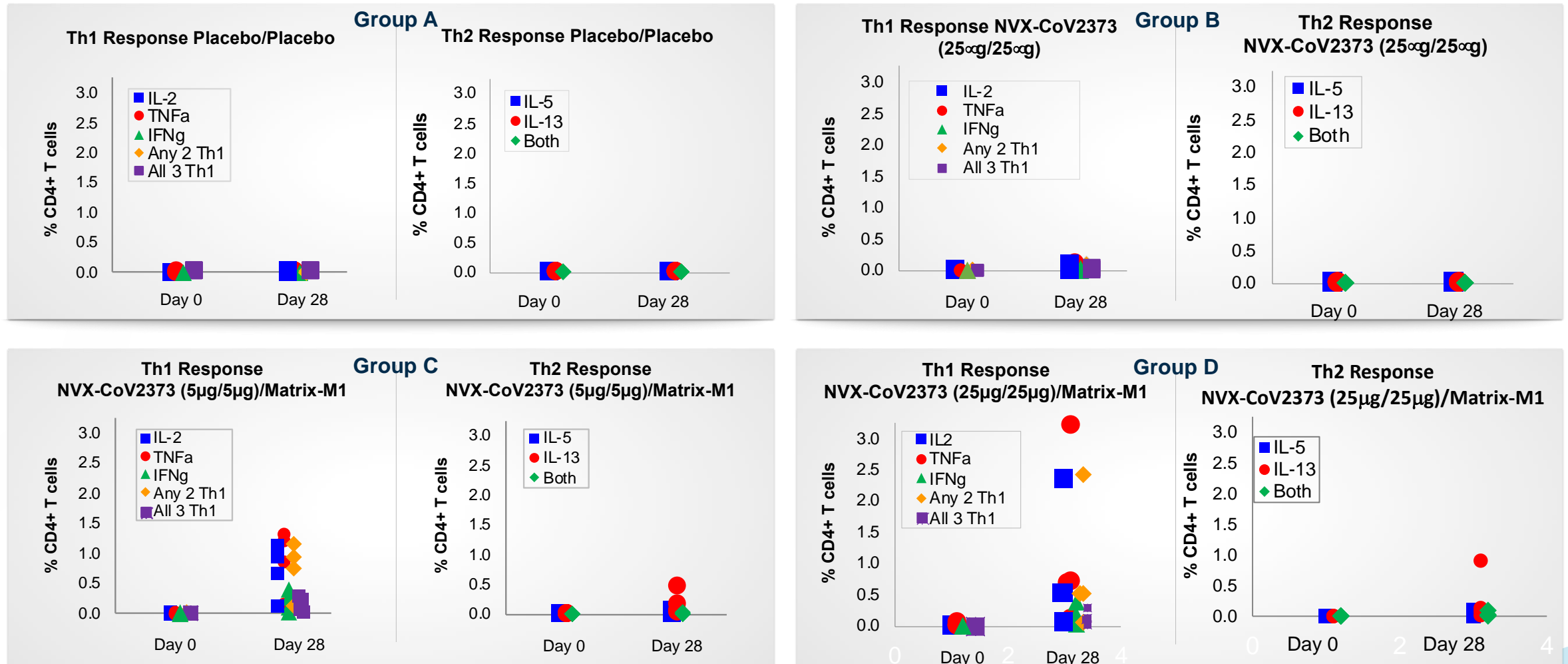


Adjuvanted dose group (C and D)



# Intracellular cytokine staining Ag-Specific CD4<sup>+</sup> T cells analysis

## Th1 response detected as predicted by non-clinical data



## Solicited Localized Symptoms



Overall, reactogenicity was mild, and vaccinations were well-tolerated

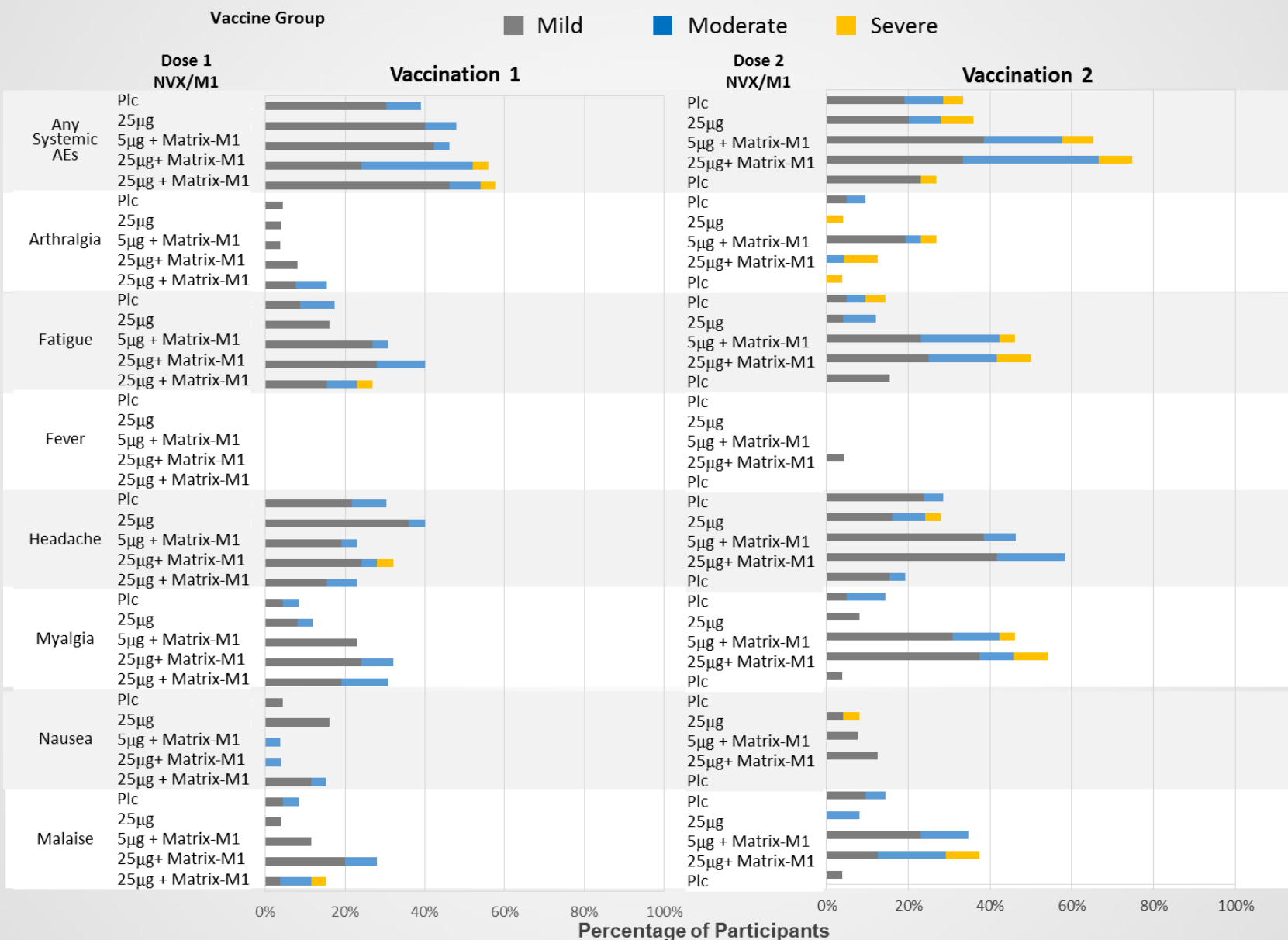
There were no vaccine refusals or dropouts due to systemic reactions

## Localized symptoms

- The majority of localized reactogenicity symptoms were mild



# Solicited Systemic Symptoms



## Systemic symptoms

- Reactogenicity increased after Dose 2
- Average duration of reactions <2 days
- Majority of reported symptoms remained at ≤ 1 grade (mild or none)

# NVX-CoV2373 Phase 1 clinical trial conclusions



## Data demonstrates a dose dependent response

- Both dosage levels induce high and comparable levels of IgG – dose-sparing
- IgG levels compared favorably to those seen in convalescent serum
- 100% IgG seroconversion rate
- Adjuvant required for optimal immune response

## Wild-type neutralization levels numerically superior to convalescent serum

- Both dosage levels induce high and comparable wild-type neutralization levels
- 100% wild-type neutralization seroconversion rate after 2<sup>nd</sup> dose
- Neutralization response is tightly correlated with IgG response

## Strong T cells response with adjuvanted vaccine

- Multifunctional CD4<sup>+</sup> T cells induced
- Largely Th1 favored phenotype

## Phase 1 demonstrated reassuring safety and reactogenicity profile

- No serious adverse events
- All unsolicited adverse event were mild or moderate
- Local and systemic reactogenicity was not dose limiting



# Q&A