

Safety and Immunogenicity of Moderna COVID-19 Vaccine (2023-2024 Formula)

Monovalent XBB.1.5 Variant Vaccine

ACIP

September 12, 2023

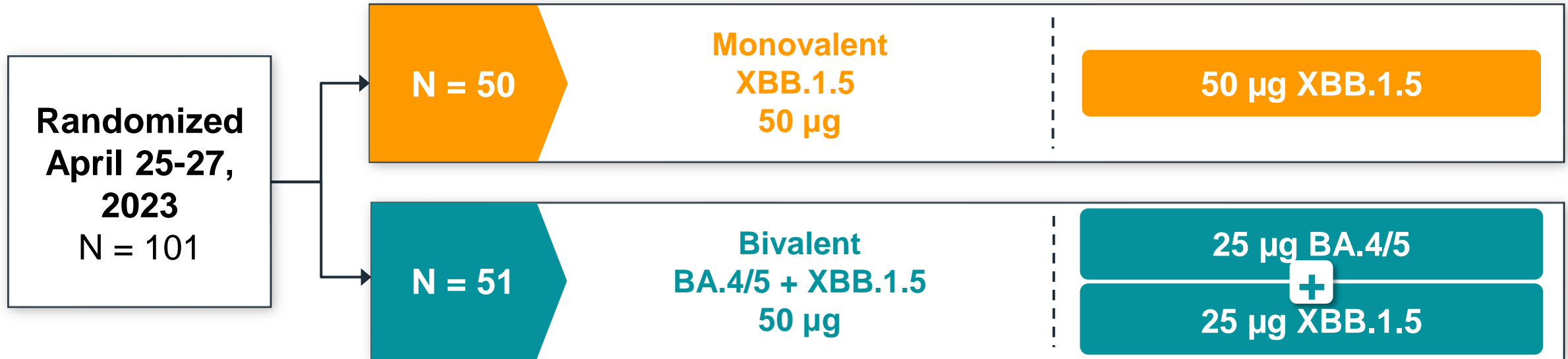
Frances Priddy, MD MPH

Moderna

Outline of Presentation

- Overview of clinical trial of XBB.1.5 vaccine
 - Design
 - Safety data
 - Immunogenicity data
- Analysis of cross neutralization data for recent variants
- Summary

Phase 2/3 Randomized Safety and Immunogenicity Study of XBB.1.5-Containing Booster in Adults ≥ 18 Years



- Participants previously received 4 doses of COVID-19 vaccine (primary series and booster of mRNA-1273 + booster of BA.4/BA.5 vaccine)
- **Focus of today's presentation will be on the monovalent XBB.1.5 vaccine selected for 2023-2024 season**
- All analyses are descriptive

Demographics and Baseline Characteristics

Study 205J, XBB.1.5 Recipients

Characteristic	5 th Dose (3 rd Booster)
	Monovalent XBB.1.5 N = 50
Mean Age – Years	51.6
Median Age – Years (range)	55 (21, 84)
≥ 65 years	11 (22.0%)
% Female	30 (60.0%)
Non-White Race	5 (10.0%)
Months between 2 nd and 3 rd Dose, median (Q1, Q3)	8.2 (7.8, 9.8)
Months between 3 rd and 4 th Dose, median (Q1, Q3)	9.8 (8.3, 10.3)
Months between 4 th and 5 th Dose, median (Q1, Q3)	8.2 (8.1, 8.3)
Prior SARS-CoV-2 Infection	34 (68.0%)

**Safety of Moderna COVID-19 Vaccine
(2023-2024 Formula)
*XBB.1.5 Monovalent Vaccine***

Local Reactions Following Booster Doses in Adults

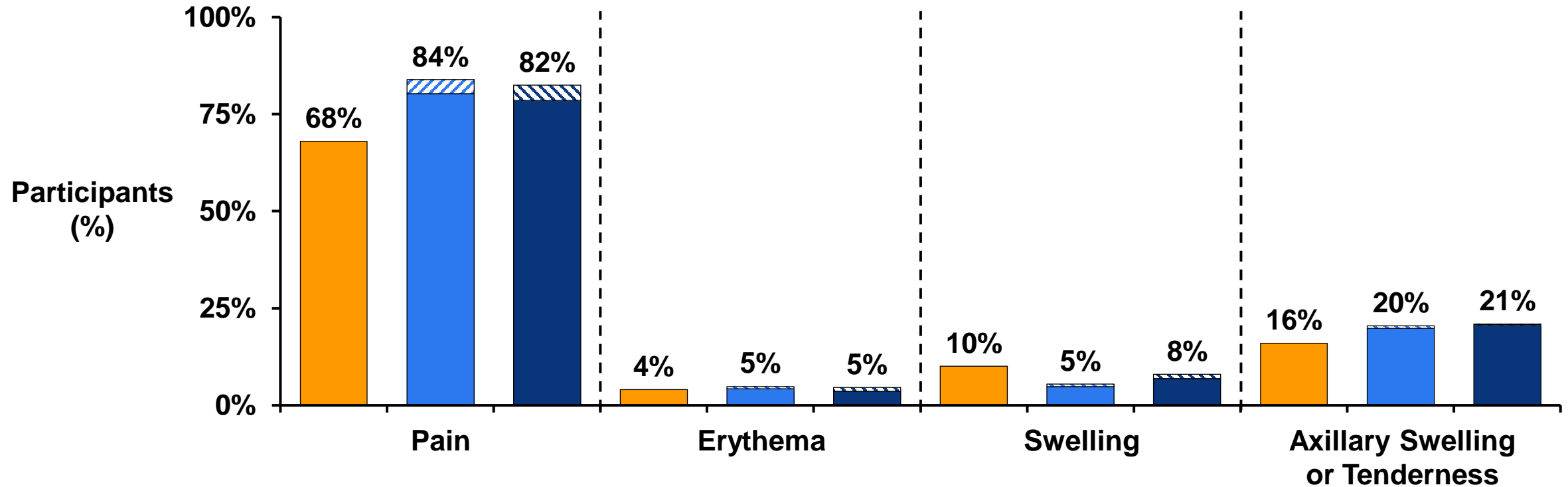
Study 205J and Study 205H, Solicited Safety Set

Monovalent XBB.1.5
N = 50

Original Vaccine
N = 167

Bivalent BA.4/BA.5
N = 508

■ Grade 1-2 ▨ Grade 3



Local reactions similar or lower than previously authorized Moderna COVID-19 vaccines

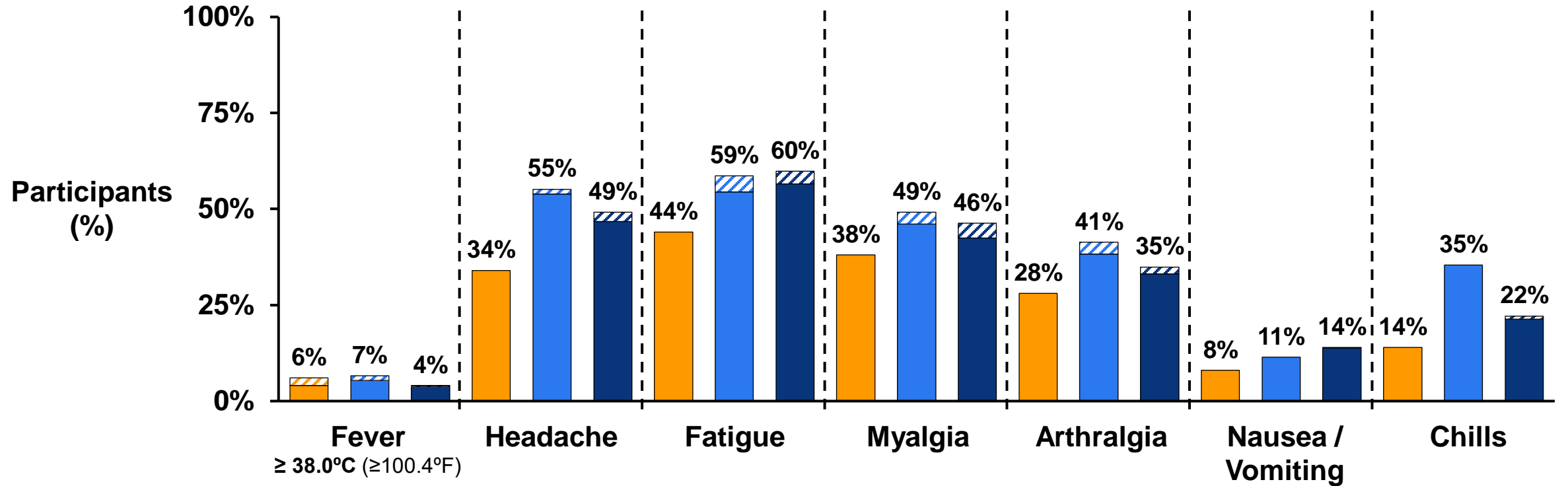
Within 7 days of injection; No Grade 4 events reported
Chalkias et al., *medRxiv*, 2022, Chu et al, *Nat Med* 28:1041, 2022

Systemic Reactions Following Booster Doses in Adults

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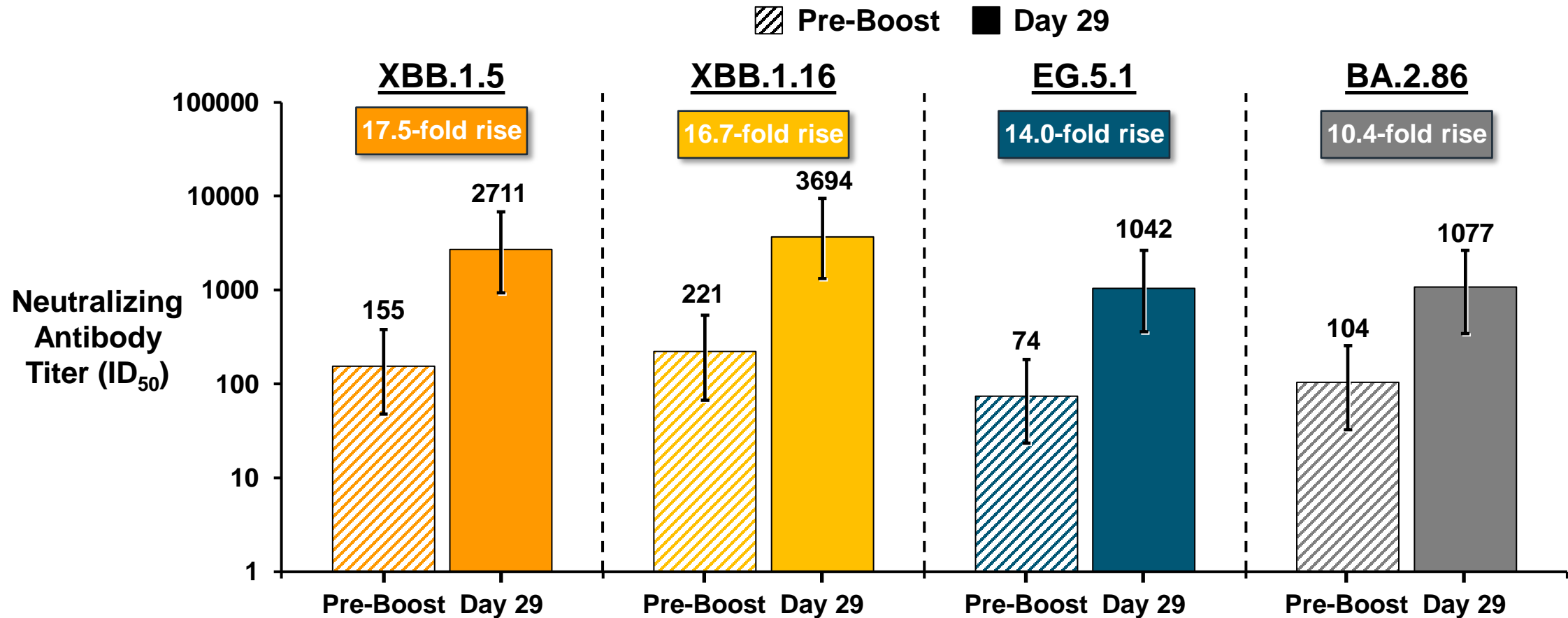
**Immunogenicity of Moderna COVID-19
Vaccine (2023-2024 Formula)
*XBB.1.5 Monovalent Vaccine***

Rapid Assessment of Neutralization Capacity of 2023-2024 XBB.1.5 Vaccine Against Emerging Variants

- Pre and post booster sera from XBB.1.5 vaccine recipients assessed against previously dominant and newly emerged variants
 - Duke assay (Lenti-PsVNA) – Day 29 sera assessed
 - Moderna research assay (VSV-PsVNA) – Day 15 sera assessed
 - Titers generally consistent between Day 15 and Day 29
- Sera tested against:
 - Prior strains: Ancestral (D614G), BA.4/BA.5
 - XBB-lineage: XBB.1.5, XBB.1.16
 - New strains: EG.5.1, FL.1.5.1, BA.2.86

Cross Neutralization Results (Day 29) After XBB.1.5 Vaccine in Adults – *Duke Assay*

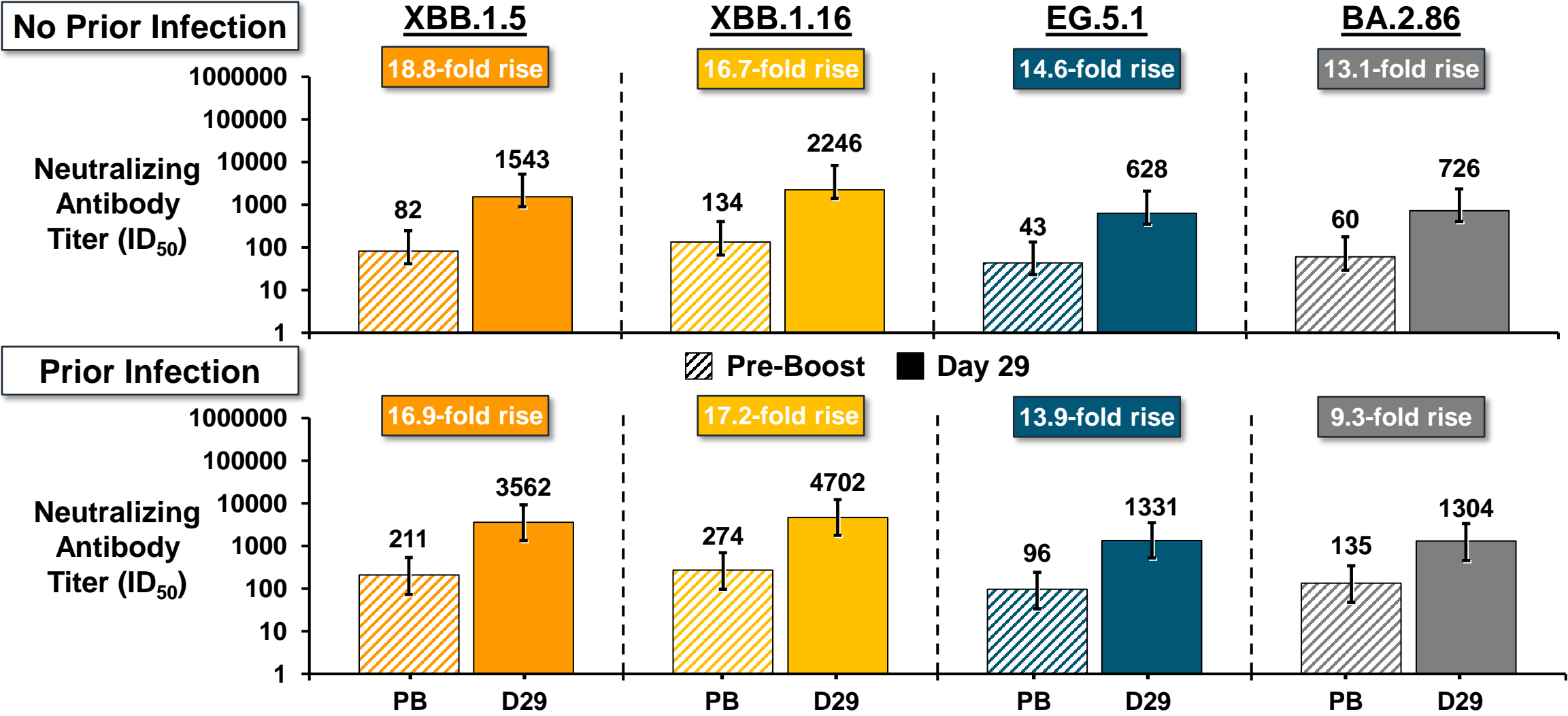
Study 205J, Per-Protocol Immunogenicity Set - All Participants



Substantial fold rise demonstrated across newer variants

Cross Neutralization Results (Day 29) After XBB.1.5 Vaccine in Adults by Baseline SARS-CoV-2 Serostatus - *Duke Assay*

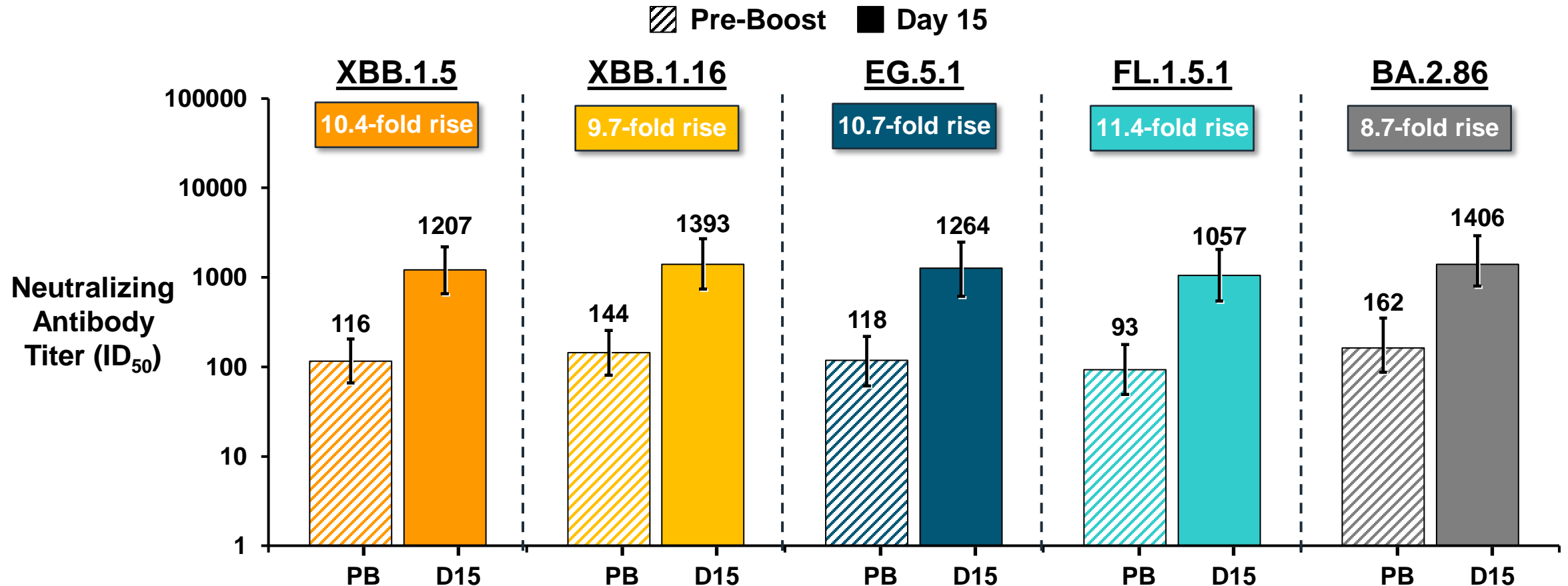
Study 205J, Per-Protocol Immunogenicity Set



Cross neutralization demonstrated regardless of prior SARS-CoV-2 infection

Cross Neutralization Results (Day 15) After XBB.1.5 Vaccine in Adults - Moderna Assay

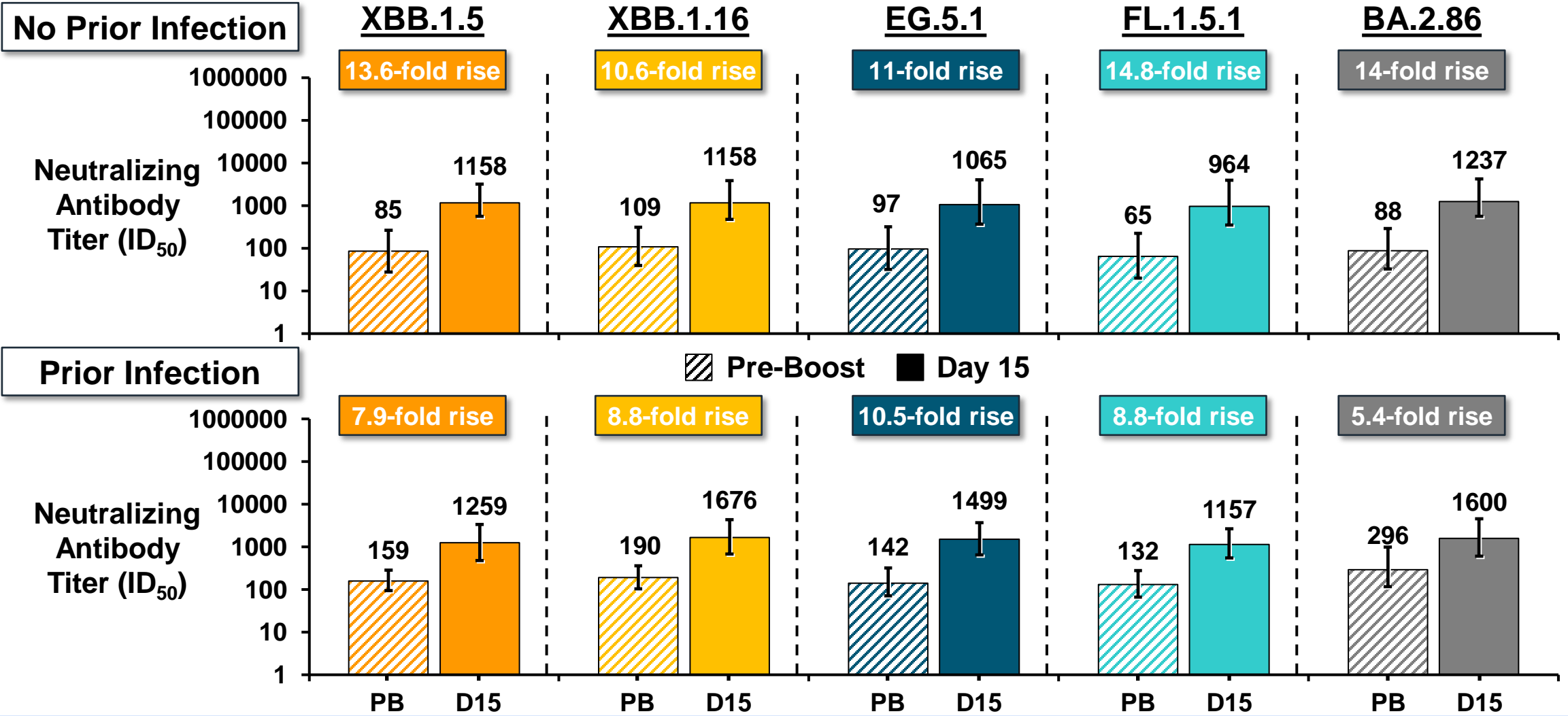
Study 205J, Subset Analysis (N = 20)



Consistent cross neutralization demonstrated for newer variants, including BA.2.86

Cross Neutralization Results (Day 15) After XBB.1.5 Vaccine in Adults by Baseline SARS-CoV-2 Serostatus - Moderna Assay

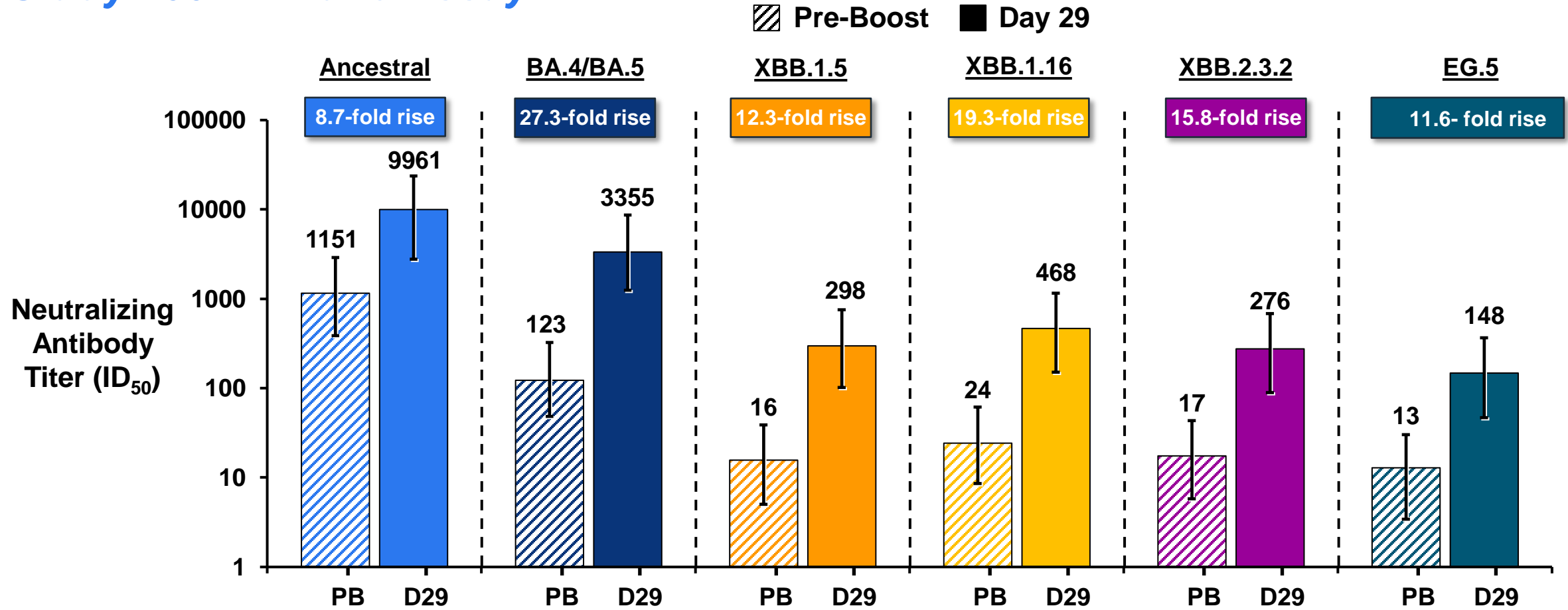
Study 205J, Subset Analysis (N=20)



Cross neutralization demonstrated regardless of prior SARS-CoV-2 infection

Cross Neutralization Results (Day 29) in Adults after Bivalent BA.4/BA.5 Vaccine

Study 205H – Duke Assay



Limited cross neutralization to newer variants after previously authorized BA.4/BA.5 bivalent vaccine

Summary

Safety and Immunogenicity of Moderna COVID-19 Vaccine (2023-2024 Formula) *XBB.1.5 Vaccine*

Clinical Study of XBB.1.5 Vaccine

- Safety profile of XBB.1.5 vaccine consistent with previously authorized vaccines
- Robust neutralizing antibody titers against XBB.1.5, XBB.1.16, EG.5.1, FL.1.5.1, and BA.2.86 measured in sera from recipients of XBB.1.5 vaccine
- XBB.1.5 vaccine is anticipated to be effective against current SARS-CoV-2 variants

Moderna's Vaccine Preparedness

- Moderna will supply an XBB.1.5 vaccine for Fall 2023
- Moderna will continue its ongoing variant monitoring and risk assessment of emerging variants

THANK YOU to Our Study Collaborators, Investigators, and Participants

- **All investigators**
- **Study site personnel**
- **Laboratory personnel**
- **Most importantly, the individuals who participated in these trials**