POS0471

Psoriatic Skin and Nail Outcomes With Guselkumab Treatment in Participants With Active and Erosive Psoriatic Arthritis: Results Through Week 24 of the Phase 3b, Randomized, Double-Blind, Placebo-Controlled APEX Study

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Key Takeaways

- In APEX, GUS demonstrated clinical improvement in psoriatic skin and nail disease at W24
- Overall, GUS-treated pts achieved high rates of complete skin (PASI 100 and IGA 0) and nail (mNAPSI 100) clearance with similar results across dosing regimens

Background

Guselkumab (GUS) is a fully human, dual-acting[1] monoclonal antibody that selectively inhibits the interleukin-23p19 subunit and is approved globally for patients with moderate-to-severe psoriasis (PsO) and active psoriatic arthritis (PsA)[2]

The ongoing, phase 3b, multicenter, randomized, double-blind, placebo (PBO)-controlled APEX study is evaluating GUS effects on clinical and structural damage progression outcomes in participants (pts) with active and erosive PsA

- A novel aspect of APEX is the inclusion of psoriatic skin and nail assessments, 2 of the 6 key PsA domains, in a PsA population

In APEX, both GUS dosing regimens (every 4 or 8 weeks [Q4W/Q8W]) were efficacious in improving PsA signs and symptoms and inhibiting structural damage progression at Week (W)24[3]

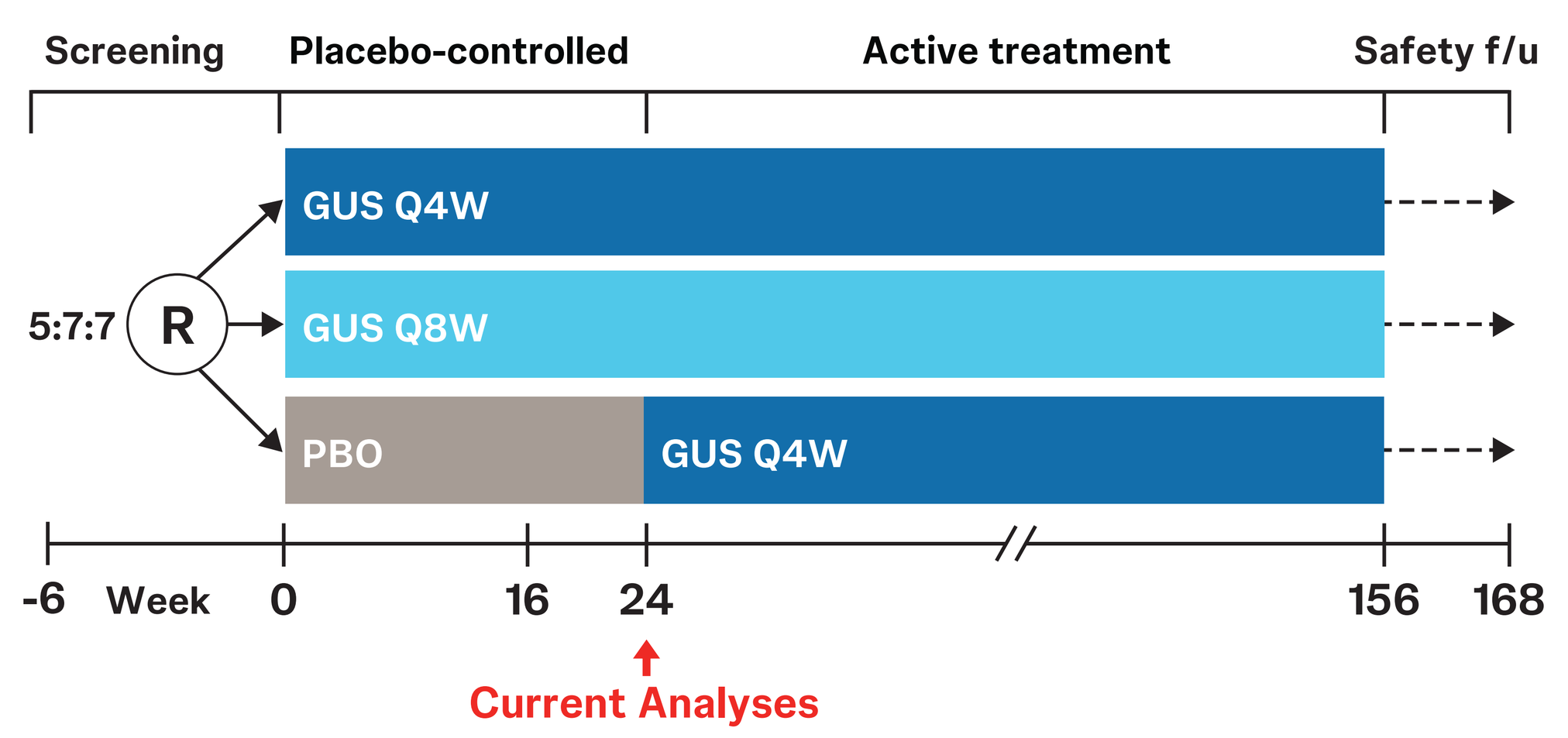
Objective

Evaluate the efficacy of GUS on psoriatic skin and nail disease through W24 in pts with active and erosive PsA in APEX

APEX Study Design and Methods

Inclusion Criteria

- ✓ Biologic-naive
- ✓ Age ≥18 years
- ✓ Active PsA ≥6 months (despite prior csDMARD, apremilast, NSAID); CASPAR criteria met
- ✓ ≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL
- ✓ ≥2 erosive joints on hand/foot radiographs
- ✓ Active plaque PsO (≥1 PsO plaque ≥2 cm and/or nail PsO)



- **Modified full analysis set (mFAS):** All randomized pts excluding those from Ukraine sites rendered unable to support key study operations due to MD; employed as the main efficacy analysis set
- **Statistical Analysis:** Pts who previously discontinued study intervention, initiated/increased dose of csDMARDs or oral corticosteroids, or initiated protocol prohibited medications/therapies for PsA were considered nonresponders or were considered to have no improvement (change=0) at the visit. Data affected by ND/MD were not used; other missing data were imputed using NRI (categorical endpoints) or not explicitly imputed (continuous endpoints).

Endpoints Assessed Through W24

Psoriatic Skin Disease Endpoints[a]

PASI 100 Response

- 100% improvement from BL in PASI
- Assesses psoriatic lesion severity and therapy response (range: 0-72)

IGA 0 Response

- IGA score of 0 (clear)
- 5-point scale used to grade psoriatic lesions (severity, score: cleared, 0; minimal, 1; mild, 2; moderate, 3; severe, 4)

Nail Disease Endpoints

mNAPSI Response and Change From Baseline[b]

- ≥50%/≥75%/100% improvement from BL in mNAPSI
- LS mean percent change from BL in mNAPSI
- Grades psoriatic nail matrix and nail bed disease (range: 0-130)

PGA-F Response[c]

- PGA-F score of 0/1 (clear/minimal) and ≥2-grade reduction from BL
- 5-point scale used to assess nail bed and nail matrix for signs of PsO (severity, score: cleared, 0; minimal, 1; mild, 2; moderate, 3; severe, 4)

*[a]Assessed in pts with BL psoriatic BSA ≥3% and IGA ≥2. [b]Among pts with a BL mNAPSI score >0. [c]Assessed in those with a PGA-F ≥2 at BL. **BL**=baseline, **BSA**=psoriatic body surface area, **CASPAR**=ClASsification criteria for Psoriatic ARthritis, **CRP**=C-reactive protein, **csDMARD**=conventional synthetic disease modifying antirheumatic drug, **f/u**=follow-up, **IGA**=Investigator's Global Assessment of psoriasis, **LS**=least squares, **MD**=major disruption (Ukraine/Russia crisis), **mNAPSI**=modified Nail Psoriasis Severity Index, **ND**=natural disaster (COVID-19 site access restrictions), **NSAID**=nonsteroidal anti-inflammatory drug, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PGA-F**=Physician's Global Assessment of Fingernail Psoriasis, **R**=randomization, **SJC**=swollen joint count, **TJC**=tender joint count.*

Results

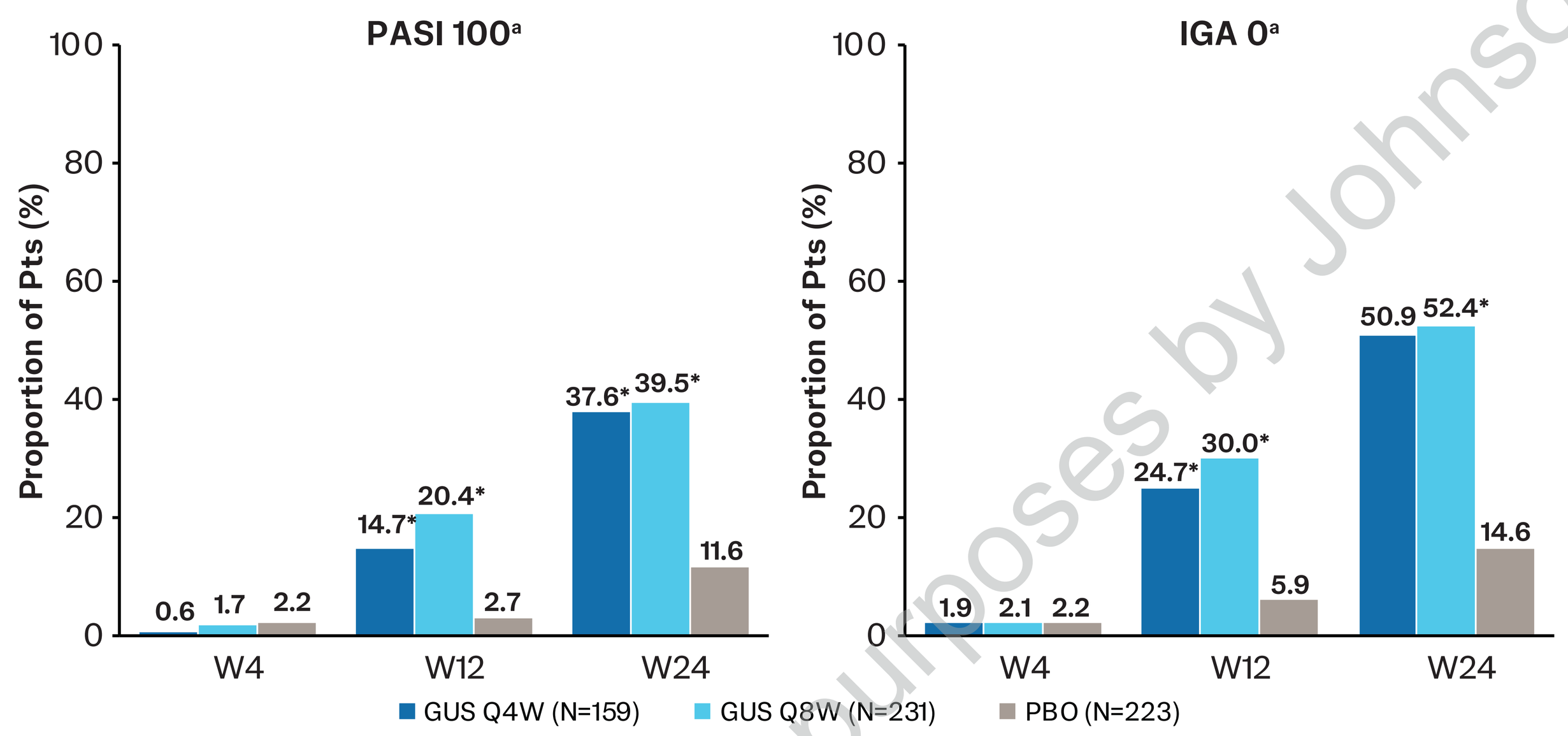
Baseline demographics were well balanced among treatment groups

- Mean baseline disease characteristics were consistent across treatment groups and indicated moderate to severe PsA activity with substantial psoriatic skin involvement

	PBO (N=376)	GUS Q4W (N=273)	GUS Q8W (N=371)	Total (N=1020)
Demographics				
Age, yrs	53.5 (13.0)	52.2 (13.2)	53.2 (12.9)	53.0 (13.0)
Male	57%	55%	54%	55%
White	83%	85%	82%	83%
BMI, kg/m^2	28.9 (5.7)	29.4 (6.0)	29.0 (5.6)	29.1 (5.7)
PsA Characteristics				
PsA Disease Duration, yrs	7.2 (6.9)	7.5 (7.1)	7.2 (7.6)	7.3 (7.2)
SJC (0-66)	11.8 (8.9)	11.6 (9.4)	12.1 (8.5)	11.9 (8.9)
TJC (0-68)	20.5 (13.9)	21.2 (14.6)	20.6 (13.4)	20.7 (13.9)
CRP, mg/dL	1.7 (2.5)	1.7 (2.9)	1.5 (2.0)	1.6 (2.5)
PsO Characteristics				
PsO Disease Duration, yrs	15.4 (13.0)	15.8 (12.5)	16.6 (13.4)	15.9 (13.0)
PASI (0-72)	8.2 (9.5)	7.6 (8.3)	8.3 (10.1)	8.1 (9.4)
% BSA	16.3 (21.5)	15.0 (19.2)	16.5 (21.9)	16.0 (21.0)
IGA				
<2, %	23	30	25	26
≥2, %	77	70	75	75
% BSA ≥3 and IGA ≥2, n (%)	223 (59)	159 (58)	231 (62)	613 (60)
Nail Disease Characteristics				
mNAPSI, N	369	269	364	1002
mNAPSI >0, n (%)	257 (70)	163 (61)	228 (63)	648 (65)
Mean (1-130)	19.4 (18.7)	23.4 (22.8)	19.8 (20.3)	20.6 (20.4)
PGA-F (0-4), N	369	268	364	1001
<2, %	57	60	59	58
≥2, %	43	40	41	42

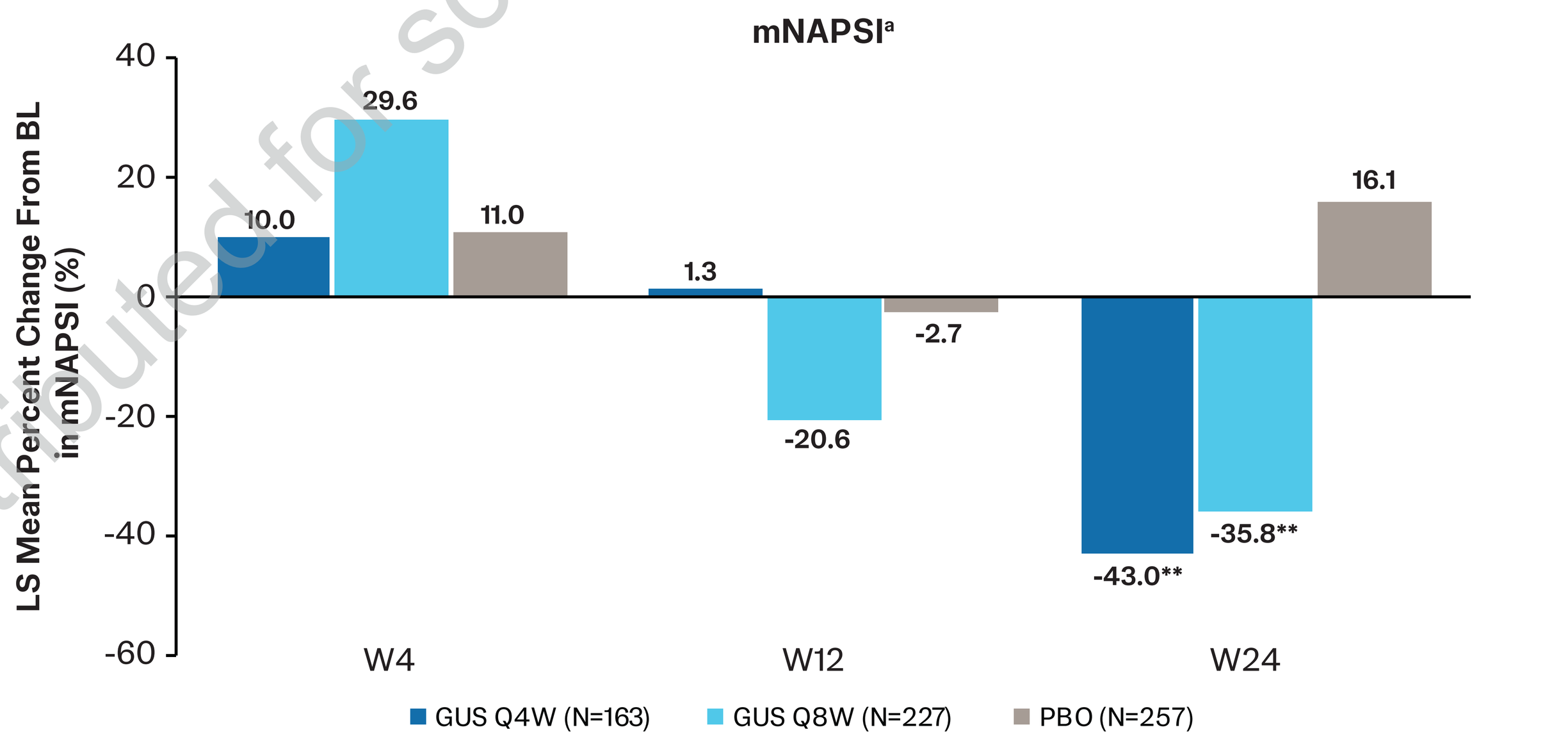
*Data shown are mean (SD) unless otherwise noted. **BMI**=body mass index.*

Higher proportions of GUS-treated pts achieved complete skin clearance (PASI 100 and IGA 0 responses) vs PBO at W12 and W24



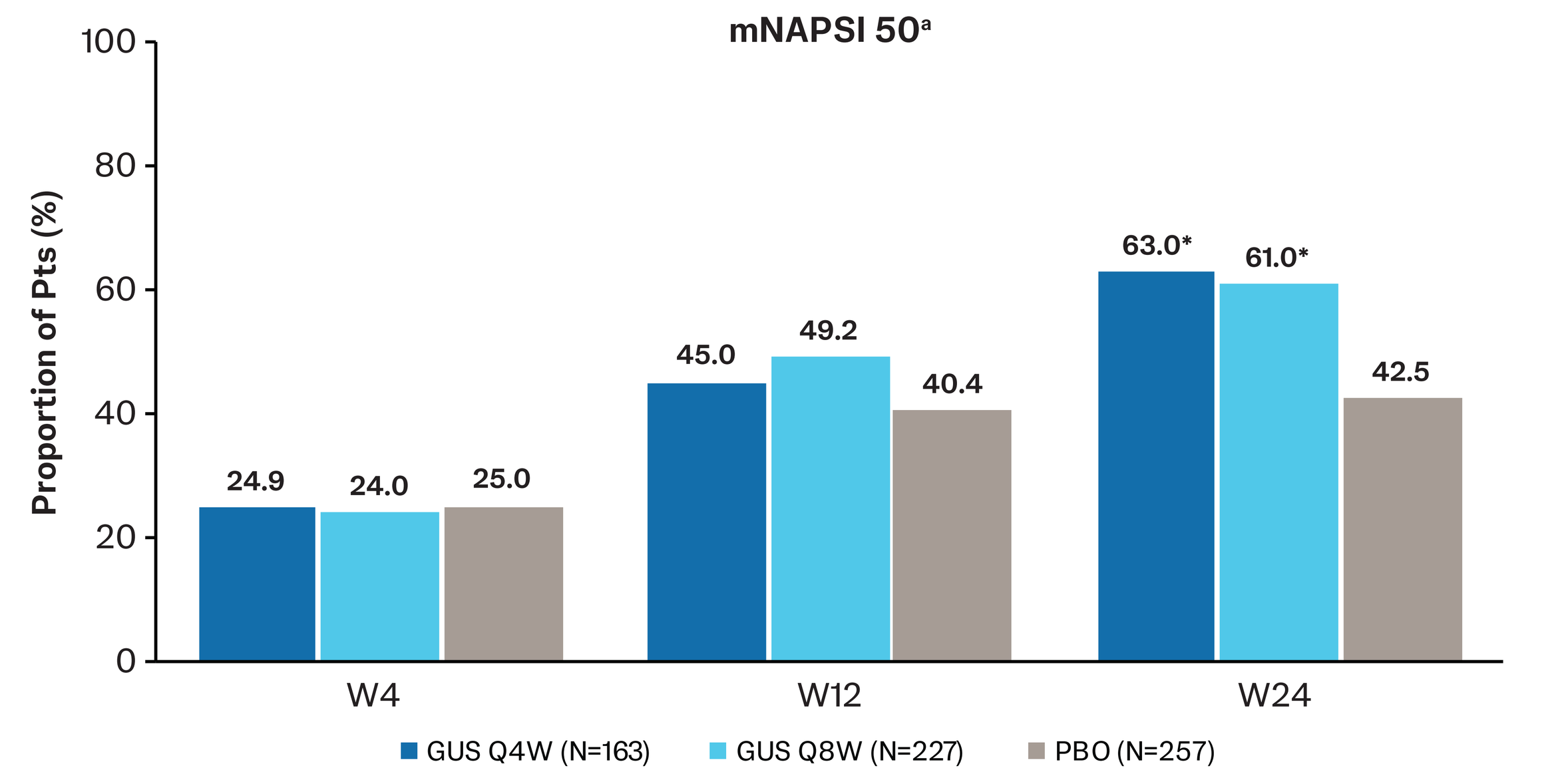
*Nominal *p<0.001 vs PBO based on GLMM; explanatory variables included treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL psoriatic BSA ≥3% and IGA ≥2. **GLMM**=Generalized Linear Mixed Model.*

At W24, GUS-treated pts had greater improvements from BL in mNAPSI compared with PBO

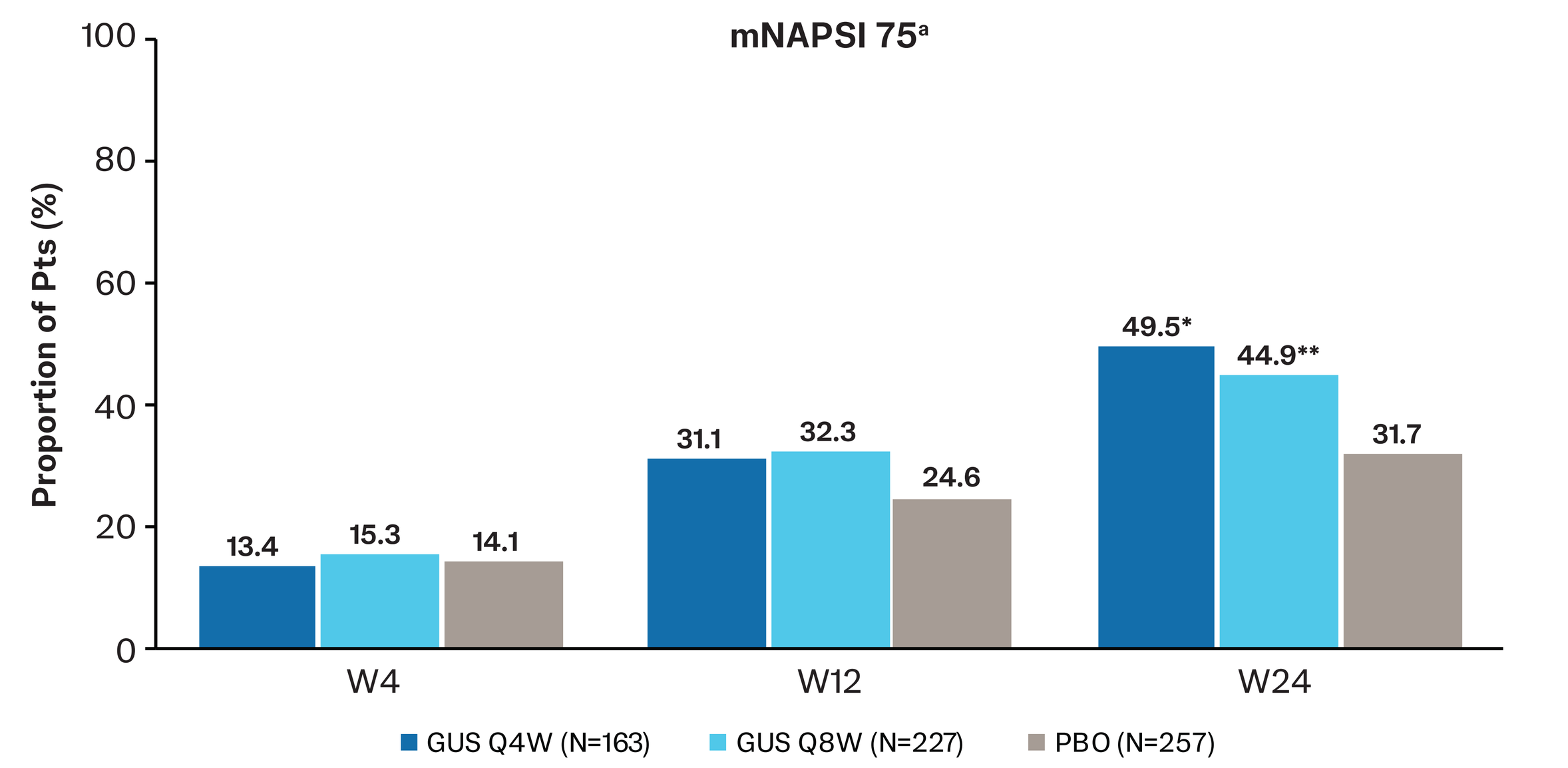


*Nominal **p<0.01 vs PBO based on MMRM; explanatory variables included baseline mNAPSI score, treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL mNAPSI score >0. **MMRM**=mixed-effect model for repeated measures.*

Greater proportions of GUS-treated pts achieved ≥50% and ≥75% improvement from BL in mNAPSI vs PBO at W24

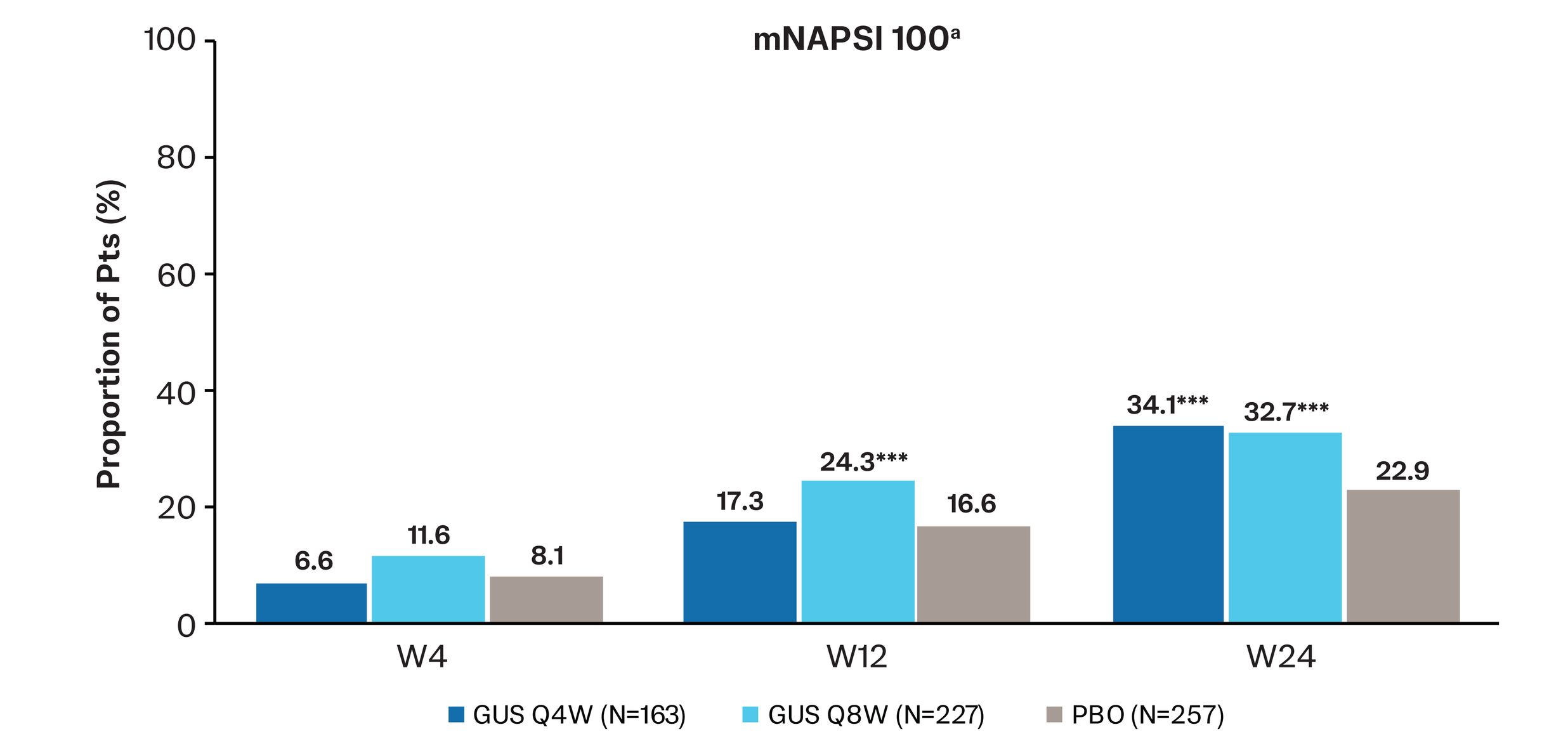


*Nominal *p<0.001 vs PBO based on GLMM; explanatory variables included treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL mNAPSI score >0.*



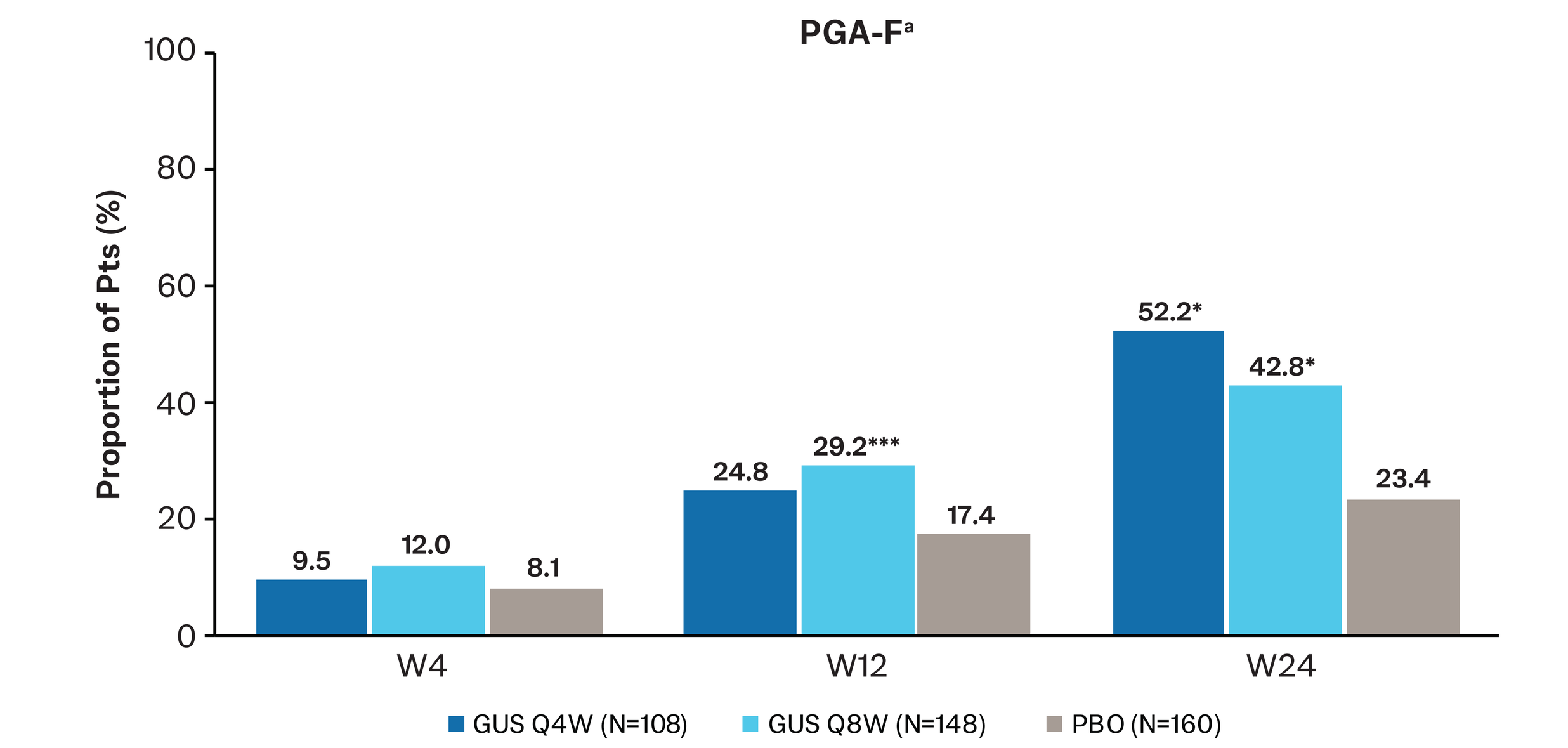
*Nominal *p<0.001 and **p<0.01 vs PBO based on GLMM; explanatory variables included treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL mNAPSI score >0.*

At W24, higher proportions of GUS-treated pts achieved complete clearance (100% improvement) of psoriatic nail disease compared with PBO



*Nominal ***p<0.05 vs PBO based on GLMM; explanatory variables included treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL mNAPSI score >0.*

Greater proportions of GUS-treated pts achieved PGA-F response at W24 compared with PBO



*Nominal *p<0.001 and ***p<0.05 vs PBO based on GLMM; explanatory variables included treatment group, visit, an interaction term of visit with treatment group, and randomization stratification level. [a]Among pts with BL PGA-F ≥2.*

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