

SPECTREM: Skin Clearance Results Through Week 48 With Guselkumab in Participants With Low Body Surface Area, Moderate Plaque Psoriasis and Palmoplantar Involvement

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Conclusions

✓ Among participants with low BSA, moderate PsO and palmoplantar involvement, GUS provided robust rates of clear/almost clear skin by Week 16 that were sustained or increased through Week 48

✓ Efficacy results were similar to those in the full SPECTREM population,^{8,9} with the limitation of a small palmoplantar cohort

Background

Historically, clinical trials evaluating use of systemic therapies for plaque psoriasis (PsO) require body surface area (BSA) involvement of $\geq 10\%$; however, the majority ($\geq 85\%$) of real-world patients with PsO have disease affecting $\leq 10\%$ BSA,² and most have involvement of high-impact sites (eg, scalp, face, genital, hands, and feet).³

- Palmoplantar PsO occurs in 12–16% of patients with PsO⁴ and is associated with significant burdens, including pain, and difficulty walking and using their hands⁵

The International Psoriasis Council expanded the criteria for systemic therapy eligibility by including patients with disease involving high-impact sites and patients who experienced failure of topical therapy,⁶ addressing potential undertreatment in these populations.⁶

SPECTREM is a phase 3b, randomized, placebo (PBO)-controlled study that evaluated the efficacy and safety of guselkumab (GUS) in participants with low BSA, moderate plaque PsO involving ≥ 1 high-impact site who had failed ≥ 1 topical therapy.⁷

- Significant improvements in skin clearance with GUS at Week 16⁷ and through Week 48⁸ were previously reported; GUS was well tolerated with no new safety signals.^{8,9}

Objective

This post hoc analysis reports efficacy of GUS through Week 48 among participants with palmoplantar involvement at baseline using:

- Investigator's Global Assessment (IGA)
- Psoriasis Area and Severity Index (PASI)
- Palmoplantar-IGA (pp-IGA)
- BSA involvement

Methods

Key inclusion criteria

- IGA=3
- BSA=2–15% with ≥ 1 plaque outside of high-impact sites
- ≥ 1 high-impact site (scalp, face, intertriginous, genital) with at least moderate severity (site-specific IGA/Physician Global Assessment [PGA] ≥ 3)
- Inadequately controlled with or intolerant of ≥ 1 prior topical therapy

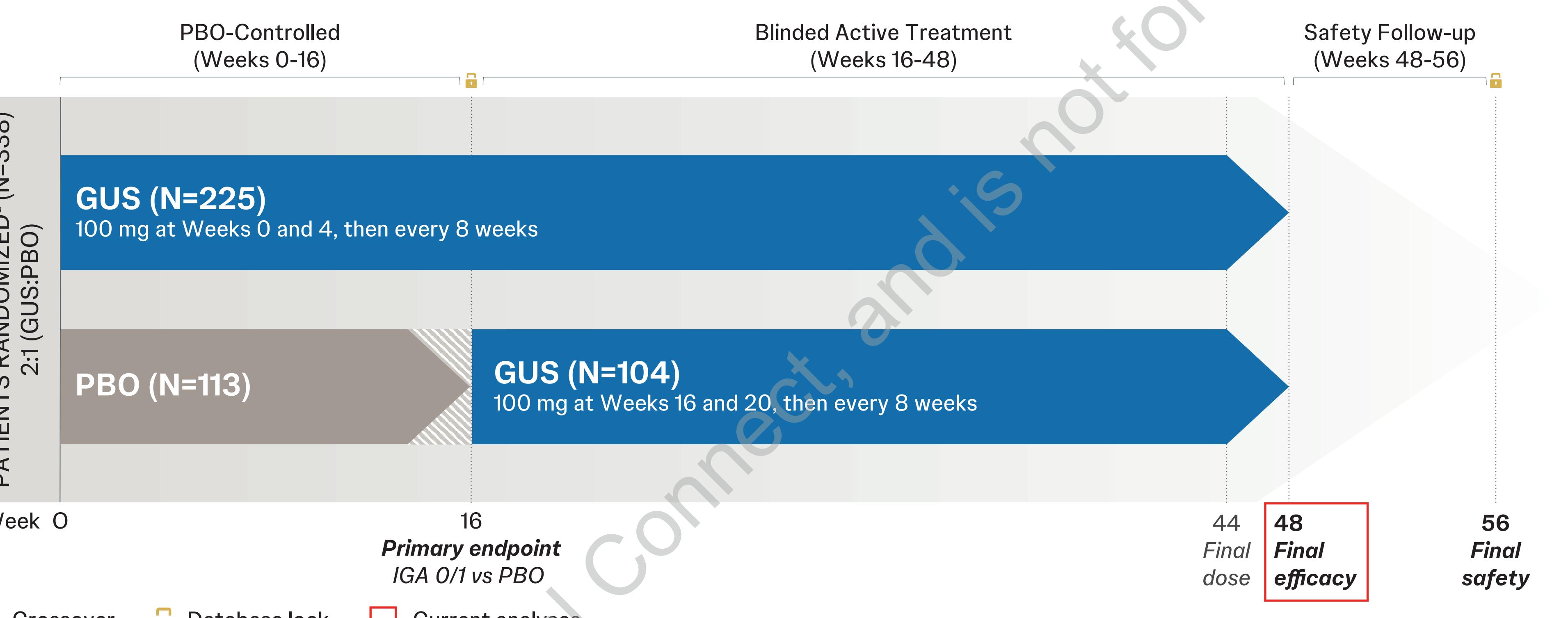
Current analysis

- Participants with pp-IGA > 0 : 8.9% (30/338)

Overall skin clearance through Week 48 was evaluated by:

- IGA 0/1 (cleared/minimal)
- IGA 0 (cleared)
- PASI 90 ($\geq 90\%$ improvement from baseline)
- PASI 100 (100% improvement from baseline)
- pp-IGA 0 (clear)
- Mean percent change in BSA involvement
- Mean percent change in PASI

*Randomization was stratified by high-impact site (scalp, face, intertriginous, genital). If participants had > 1 qualifying high-impact site at baseline, they were allocated to the site that was most severe, as determined by the participant.



Results

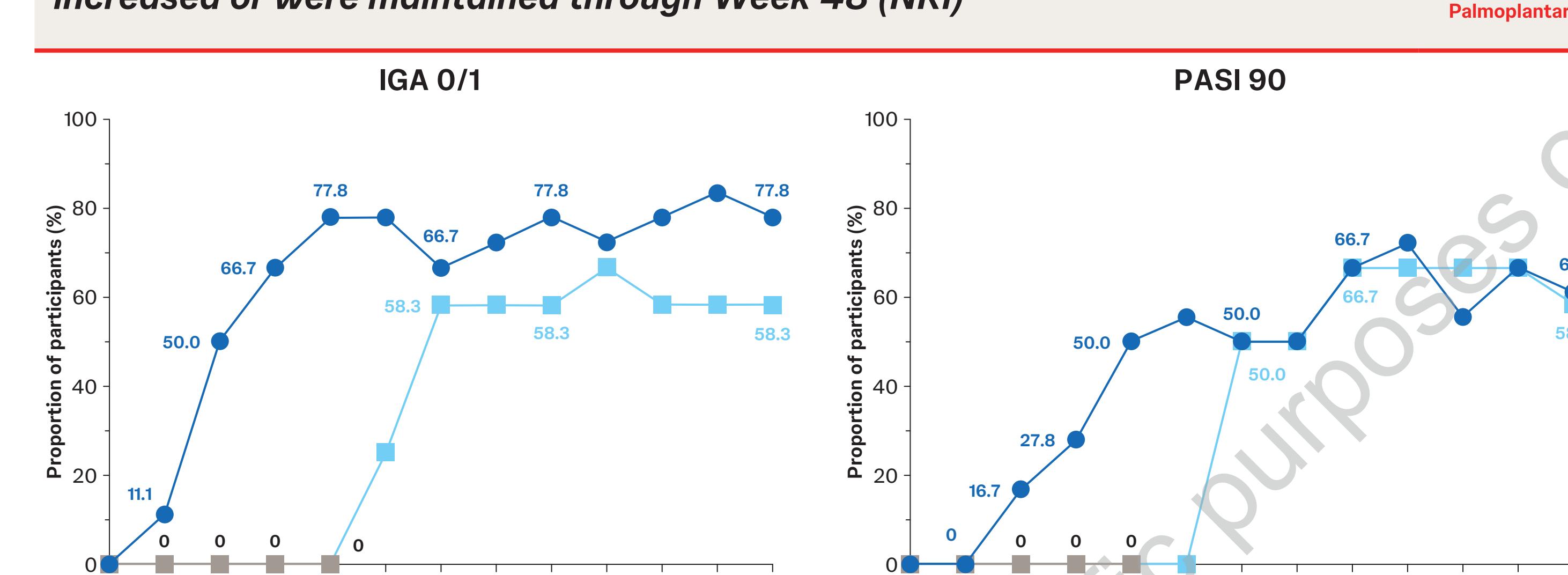
Baseline demographics and disease characteristics among participants with palmoplantar PsO were generally balanced between the PBO and GUS groups

Baseline Characteristics	PBO (N=12)	GUS (N=18)	Total (N=30)
Demographics			
Age, yrs	42.8 (11.3)	55.8 (15.2)	50.6 (15.0)
Male, n (%)	8 (66.7%)	12 (66.7%)	20 (66.7%)
Race, White, n (%)	10 (83.3%)	13 (72.2%)	23 (76.7%)
Weight, kg	91.3 (25.1)	85.1 (17.7)	87.6 (20.8)
BMI, kg/m ²	32.8 (7.9)	29.2 (5.3)	30.6 (6.6)
Disease Characteristics			
PsO disease duration, yrs	16.5 (12.7)	17.6 (15.5)	17.2 (14.2)
IGA, moderate (3), n (%)	12 (100%)	17 (94.4%) ^b	29 (96.7%)
BSA, % ^c	8.6 (2.9)	6.6 (2.8)	7.4 (3.0)
PASI (0–72) ^d	10.1 (3.1)	8.5 (2.8)	9.1 (3.0)
ss-IGA ≥ 1 , n (%)	9 (75.0%)	11 (61.1%)	20 (66.7%)
f-IGA ≥ 1 , n (%)	8 (66.7%)	8 (44.4%)	16 (53.3%)
i-IGA ≥ 1 , n (%)	7 (58.3%)	11 (61.1%)	18 (60.0%)
s-IGA-G ≥ 1 , n (%)	5 (41.7%)	11 (61.1%)	16 (53.3%)
Nail PsO, n (%)	7 (58.3%)	8 (44.4%)	15 (50.0%)
Previous Medication Use			
Topical agents, n (%) ^e	12 (100%)	18 (100%)	30 (100%)
Phototherapy, n (%) ^f	1 (8.3%)	2 (11.1%)	3 (10.0%)
Conventional systemics, n (%) ^g	2 (16.7%)	1 (5.6%)	3 (10.0%)
Advanced orals, n (%) ^h	0	1 (5.6%)	1 (3.3%)
Methotrexate, n (%)	1 (8.3%)	0	1 (3.3%)

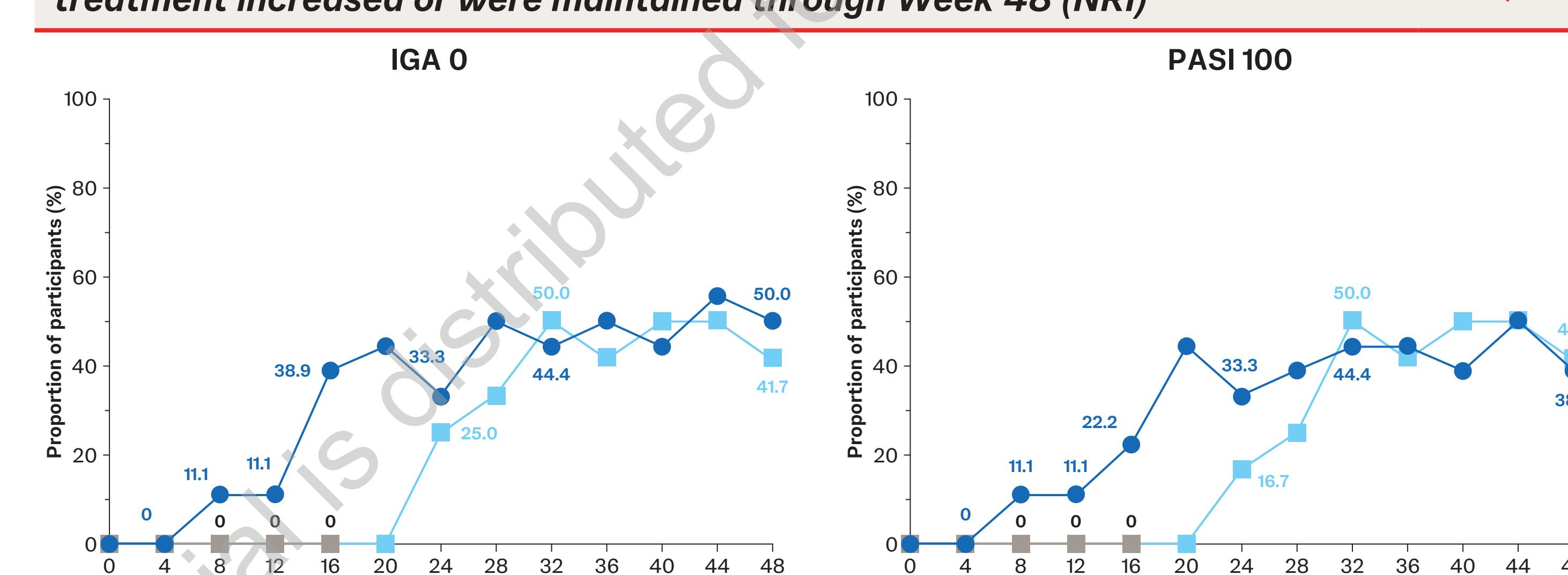
• More than 50% of those with palmoplantar PsO also had scalp, facial, intertriginous, genital, and/or nail PsO

^aData shown are mean (standard deviation) unless otherwise noted. ^bOne GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. ^cMedian (interquartile range) BSA was 8.0% (6.6–10.5), 6.0% (4.0–8.5), and 7.0% (5.0–8.0%), respectively. ^dMedian (interquartile range) PASI was 9.8% (2.2–25.6), 6.6% (4.0–10.3), and 9.0% (6.6–10.7), respectively. ^eTopical, calcineurin, keratolytic, tar, PUVa, ultraviolet B, PUVa, methotrexate, cyclosporine, calcineurin, ^fTopical, calcineurin, methotrexate, ^gBody mass index. ^hf-IGA=facial IGA; i-IGA=intertriginous IGA; s-IGA=scalp-specific IGA; ss-IGA=scalp-specific IGA.

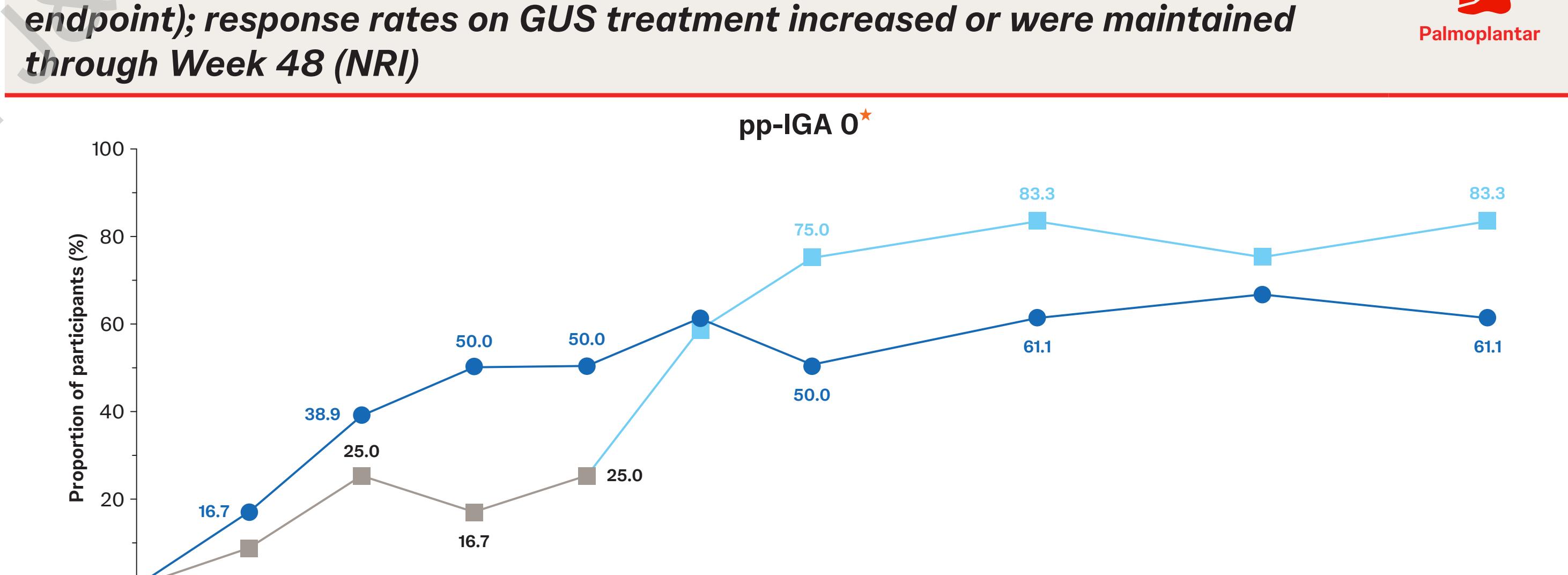
Response rates among participants with palmoplantar PsO on GUS treatment increased or were maintained through Week 48 (NRI)



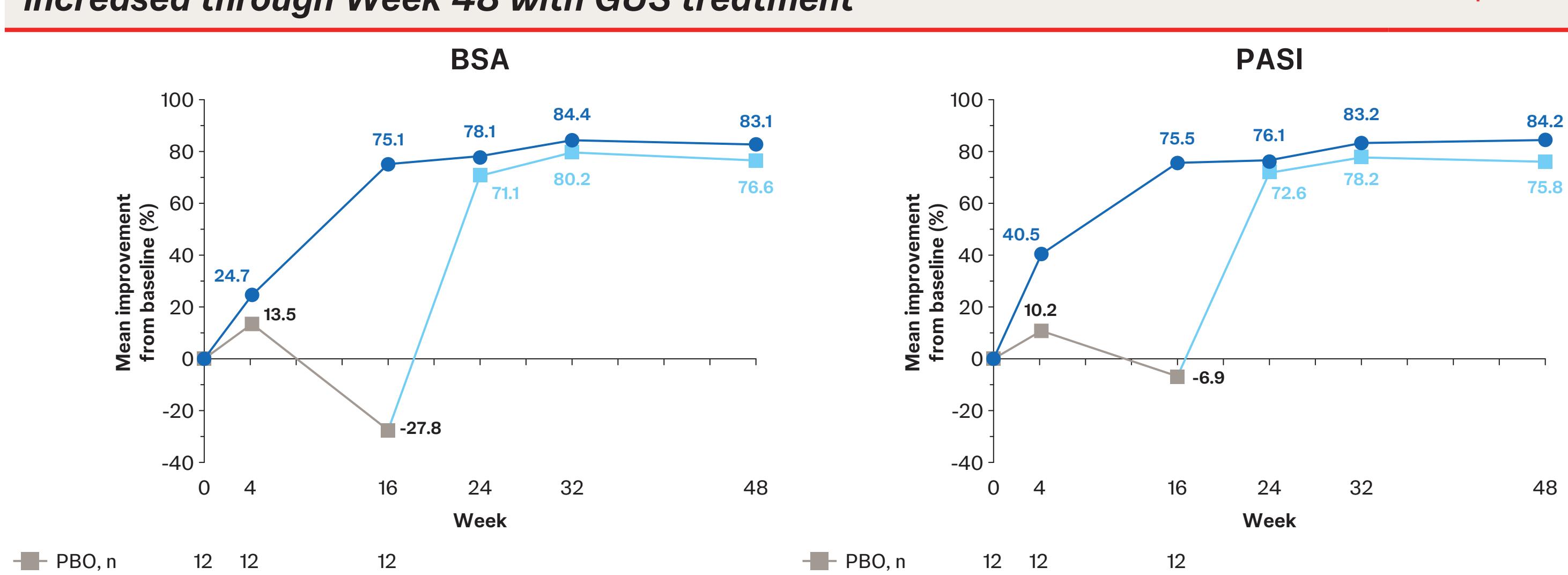
Nearly 4 out of 10 GUS-randomized participants with palmoplantar PsO achieved IGA 0 (complete skin clearance) at Week 16; response rates on GUS treatment increased or were maintained through Week 48 (NRI)



Half of GUS-randomized participants with palmoplantar PsO achieved complete skin clearance on hands and feet at Week 16 (prespecified efficacy endpoint); response rates on GUS treatment increased or were maintained through Week 48 (NRI)



Mean BSA and PASI improved by $>75\%$ at Week 16 among GUS-randomized participants with palmoplantar PsO; improvements were sustained or increased through Week 48 with GUS treatment



Photographic skin clearance journey for a participant with palmoplantar PsO randomized to GUS



Photographic skin clearance journey for a participant with palmoplantar PsO randomized to PBO

