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SPECTREM: Guselkumab Skin Clearance and Patient-Reported Outcome Results Across Skin and Joint Symptoms Through Week 48 in Low Body Surface Area, Moderate Plaque Psoriasis With at Least One Moderate High-Impact Site Involved

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Background

Historically, clinical trials evaluating use of systemic therapies for plaque psoriasis (PsO) require body surface area (BSA) involvement of ≥10%[1]; however, the majority (>85%) of real-world PsO patients have disease affecting ≤10% BSA,[2] and most have involvement of high-impact sites[3] which is often associated with poor quality of life[2,3] and a higher risk of developing psoriatic arthritis (PsA)[4]

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 regardless of BSA involvement,[5] 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]

- GUS was well tolerated and demonstrated significant improvements in skin clearance and patient-reported outcomes (PROs) versus PBO at Week 16

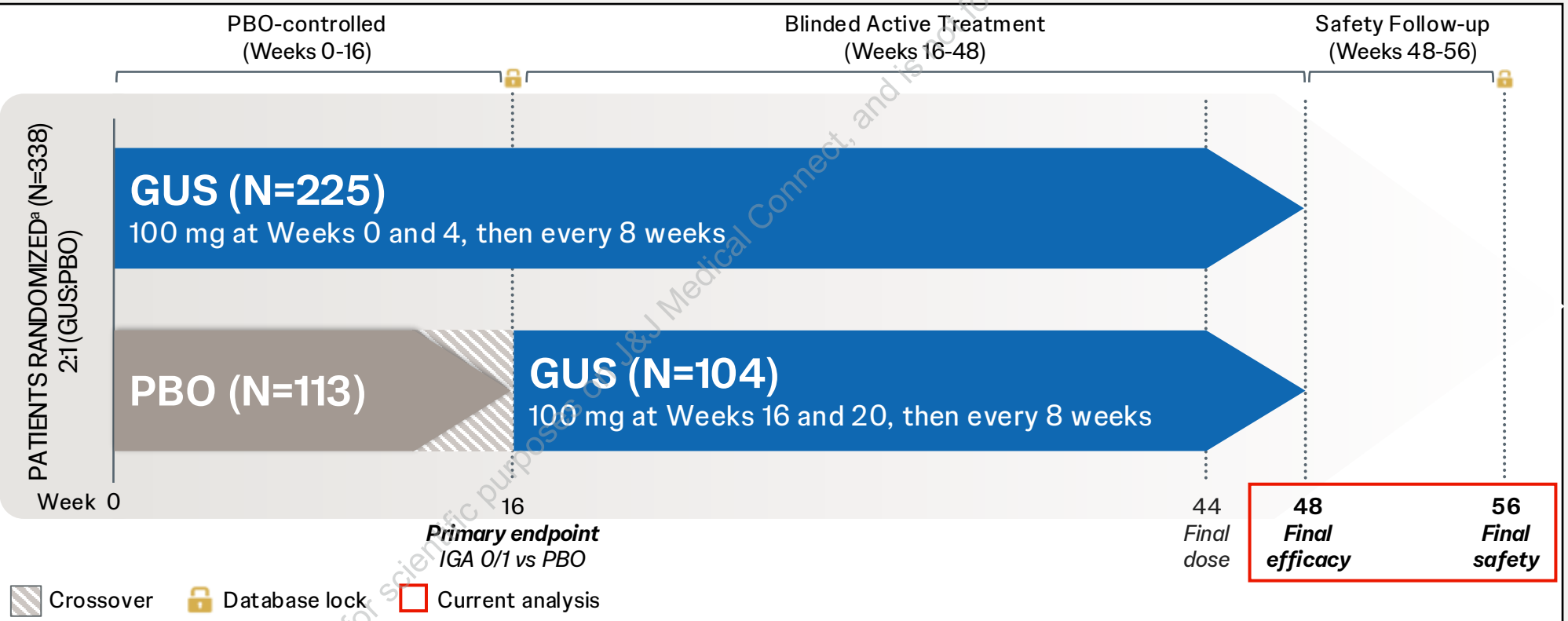
Objective

This analysis reports efficacy and PRO results at Week 48 and safety outcomes through Week 56 with GUS treatment from the final SPECTREM database lock

Methods

SPECTREM – Study Design

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/PGA ≥3)
- Inadequately controlled with or intolerant of ≥1 prior topical therapy



Overall skin clearance through Week 48 was evaluated by:
- IGA 0/1 (clear/minimal) response rates
- PASI 90 (≥90% improvement vs baseline) response rates
- Mean percent improvement in BSA affected
- Mean percent improvement in PASI

PROs were assessed by:
- DLQI 0/1 (no effect on QoL[8]) response rates
- Mean PSSD itch score
- Mean PsAID-12 score among participants identified as having PsA at screening (ie, history of rheumatologist-diagnosed PsA or PEST ≥3)

[a]*Randomization was stratified by high-impact site. 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.* ***DLQI****=Dermatology Life Quality Index,* ***IGA****=Investigator's Global Assessment,* ***PASI****=Psoriasis Area and Severity Index,* ***PEST****=Psoriasis Epidemiology Screening Tool;* ***PGA****=Physician's Global Assessment;* ***PsAID-12****=Psoriatic Arthritis Impact of Disease-12;* ***PSSD****=Psoriasis Symptoms and Signs Diary,* ***QoL****=quality of life.*

Results

Baseline demographics and disease characteristics were generally balanced between the PBO and GUS groups

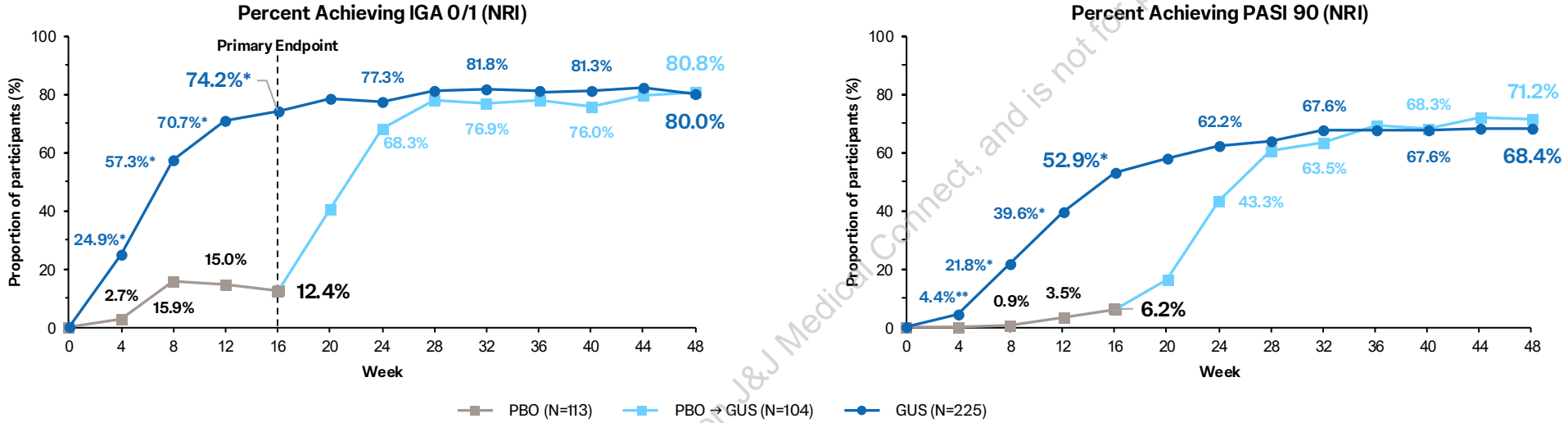
Baseline Characteristics		PBO (N=113)	GUS (N=225)	Total (N=338)
Demographics				
	Age, yrs	44.5 (14.9)	47.0 (14.7)	46.2 (14.8)
	Male, n (%)	57 (50.4%)	116 (51.6%)	173 (51.2%)
	Race, White, n (%)	83 (73.5%)	166 (73.8%)	249 (73.7%)
	Weight, kg	87.4 (20.6)	88.4 (22.4)	88.1 (21.8)
	BMI, kg/m^2	31.0 (7.5)	30.9 (7.5)	30.9 (7.5)
Disease Characteristics				
	PsO disease duration, yrs	14.0 (11.9)	18.4 (14.9)	16.9 (14.1)
	IGA, moderate (3), n (%)	113 (100%)	224 (99.6%)[b]	337 (99.7%)
	BSA, %[c]	7.5 (3.7)	7.6 (3.7)	7.6 (3.7)
	PASI (0-72)	9.0 (3.9)	9.1 (3.8)	9.0 (3.8)
	DLQI score (0-30)[d]	11.9 (6.0)	11.4 (7.0)	11.5 (6.7)
	PSSD itch score (0-10)[d]	6.8 (2.0)	6.7 (2.2)	6.8 (2.2)
	PsA[e], n (%)	26 (23.0%)	45 (20.0%)	71 (21.0%)
	PsAID-12 in participants with PsA (0–10)	4.4 (2.6)	5.8 (2.2)	5.3 (2.4)
Previous Medication Use				
	Topical agents, n (%)[f]	113 (100%)	225 (100%)	338 (100%)
	Phototherapy, n (%)[g,h]	16 (14.3%)	46 (20.5%)	62 (18.5%)
	Conventional systemics, n (%)[g,i]	15 (13.4%)	31 (13.8%)	46 (13.7%)
	Advanced orals, n (%)[g,j]	4 (3.6%)	11 (4.9%)	15 (4.5%)

Data shown are mean (SD) unless otherwise noted. [b]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; [c]Median (interquartile range) BSA was 7.0% (4.5-10.1%), 7.2% (4.3-10.7%), and 7.0% (4.3-10.5%), respectively; [d]PBO N=112; [e]Participants with a history of rheumatologist-diagnosed PsA or PEST ≥3 at screening; PsAID-12 reported only in participants with PsA; [f]Topical, anthralin, keratolytics, tar; [g]PBO N=112, GUS N=224, Total N=336; [h]PUVA, UVB; [i]PUVA, methotrexate, cyclosporine, acitretin; [j]Apremilast, deucravacitinib. ***BMI****=body mass index,* ***PUVA****=psoralen plus ultraviolet A,* ***SD****=standard deviation,* ***UVB****=ultraviolet B.*

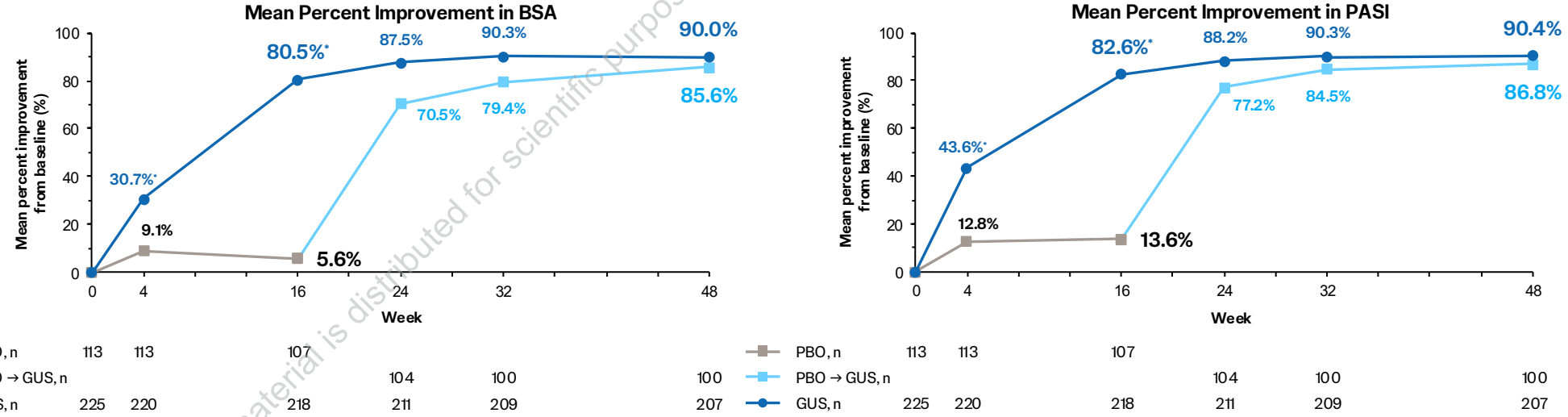
More than 90% of GUS-randomized participants completed treatment with study agent through Week 48

- Of the 338 total participants, 225 and 113 were randomized to GUS and PBO, respectively
  - 104 PBO-randomized participants crossed over to receive GUS at Week 16
- Participants who completed treatment with study agent through Week 48:
  - 91.1% (205/225) of GUS-randomized participants
  - 85.0% (96/113) of PBO-randomized participants who crossed over to GUS at Week 16
- Participants who completed study participation through Week 56:
  - 92.4% (208/225) of GUS-randomized participants
  - 84.1% (95/113) of PBO-randomized participants who crossed over to GUS at Week 16

Significantly greater improvements in efficacy measures were seen with GUS vs PBO as early as Week 4; improvements with GUS treatment increased or were sustained through Week 48, when ~70-80% of participants achieved clear or almost clear skin, and mean percent improvements in BSA and PASI were >85%

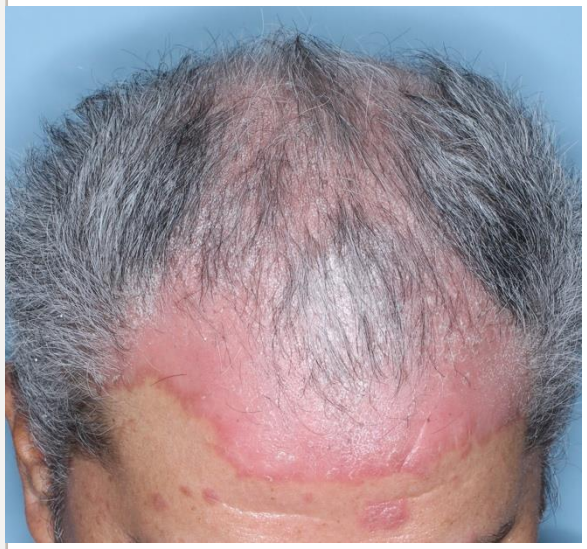
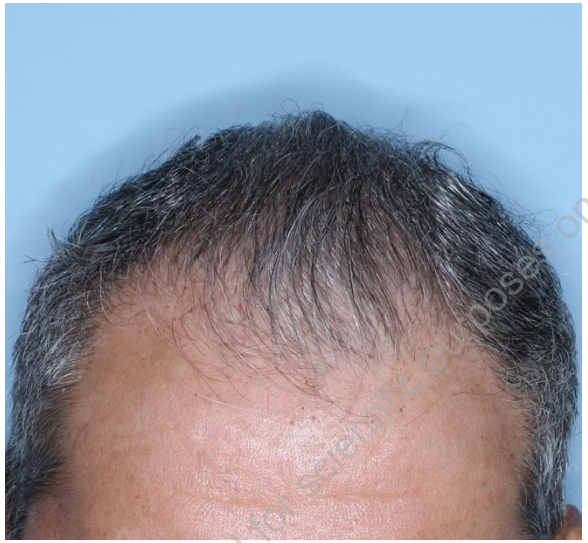
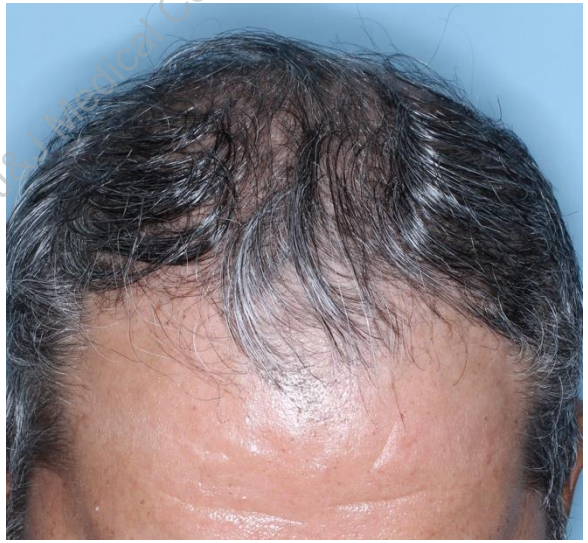
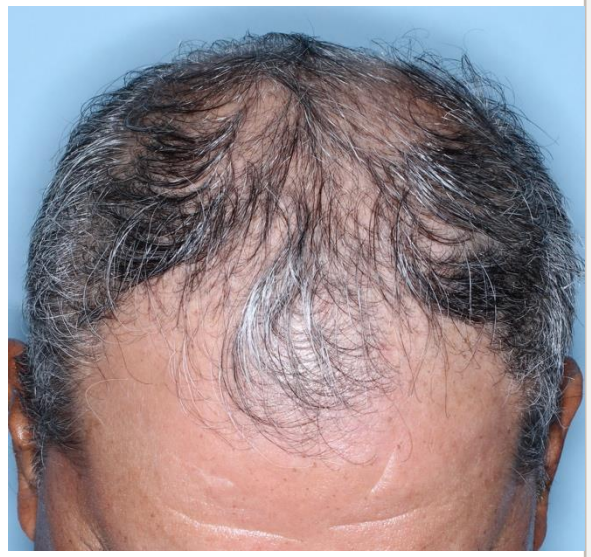


*p<0.001, **p<0.05 GUS vs PBO based on the Cochran-Mantel-Haenszel (CMH) test stratified by high-impact site. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO → GUS group. **NRI**=nonresponder imputation.

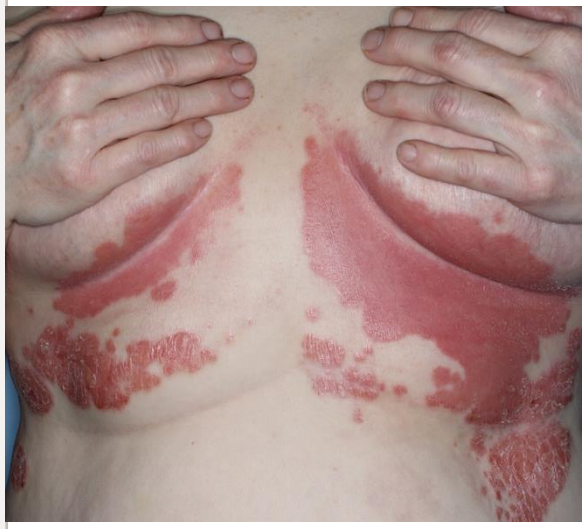
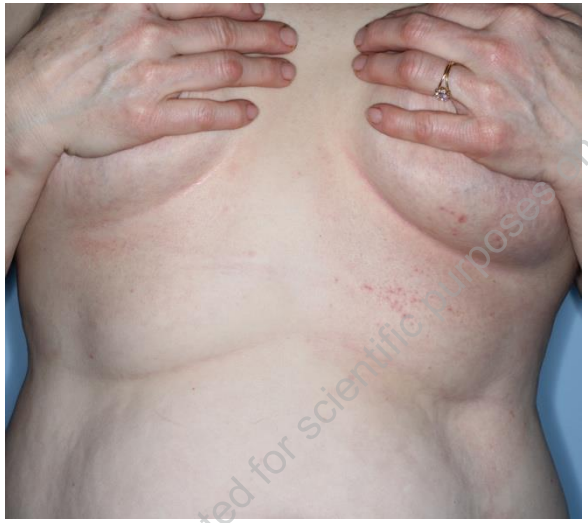
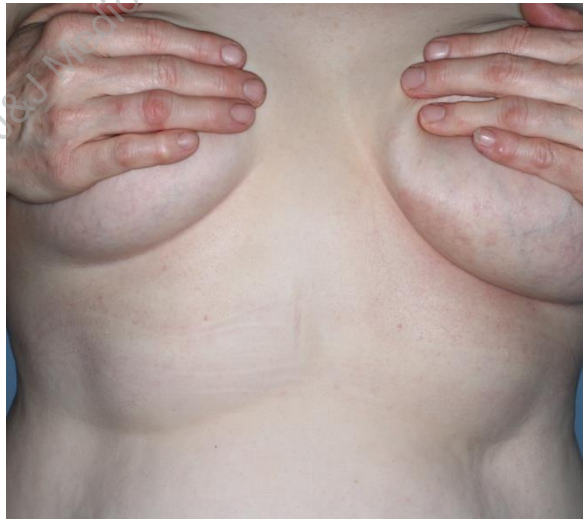
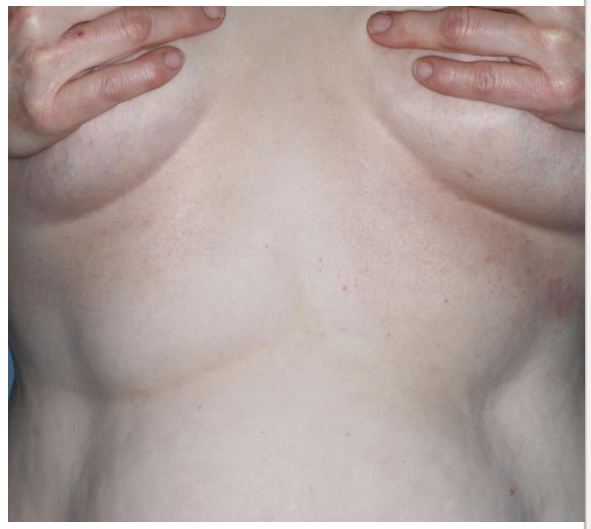


*p<0.001 GUS vs PBO change from baseline based on the mixed models for repeated measures (MMRM) with treatment group, visit, baseline score, high-impact site, and interaction terms of visit with treatment group and baseline score as explanatory variables. Participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were assigned a change from baseline of 0. Participants with missing data were not explicitly imputed, they were accounted for in the analysis model. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO → GUS group.

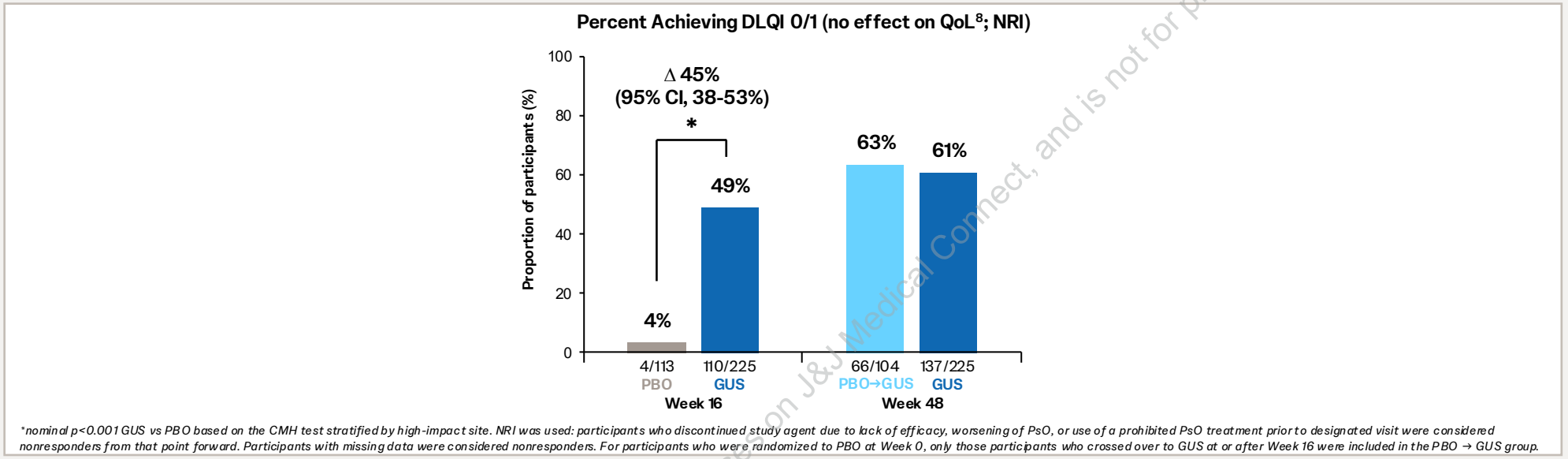
Photographic skin clearance journey for a participant randomized to GUS

Week 0	Week 16	Week 32	Week 48
			

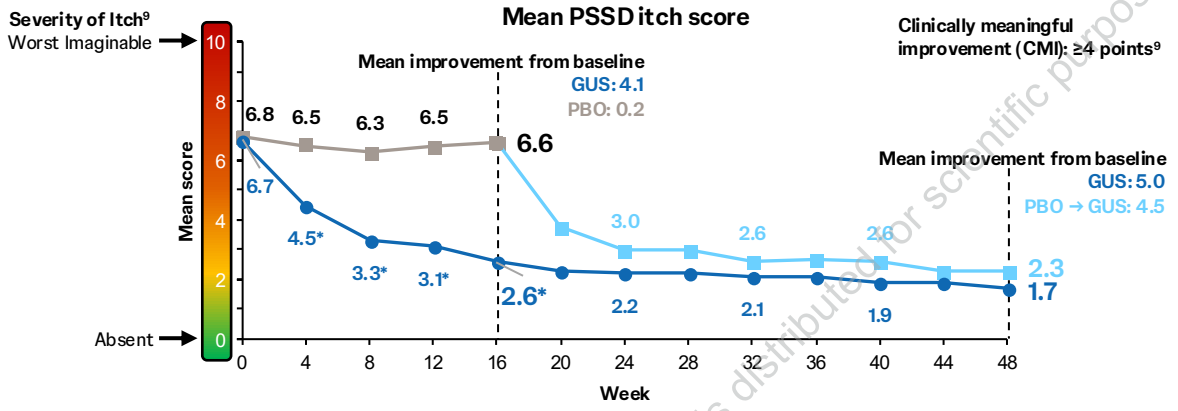
Photographic skin clearance journey for a participant randomized to GUS

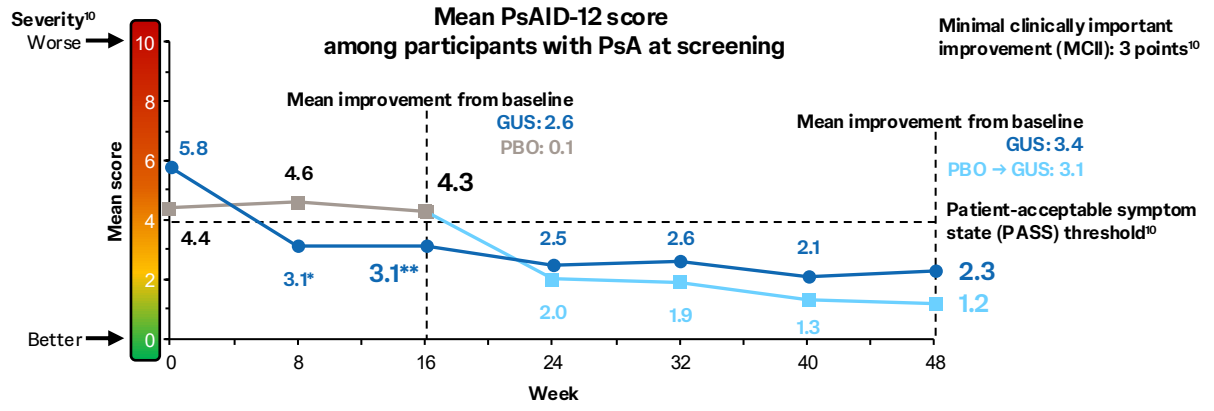
Week 0	Week 16	Week 32	Week 48
			

At Week 48, >60% of participants achieved DLQI 0/1 (no effect on QoL[8]); meaningful improvements in mean PSSD itch (≥4.5 points) & PsAID-12 scores (>3 points) were achieved by Week 24 and maintained or improved through Week 48



*nominal p<0.001 GUS vs PBO based on the CMH test stratified by high-impact site. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO → GUS group.





*nominal p<0.001, **nominal p=0.006 GUS vs PBO change from baseline based on the MMRM with treatment group, visit, baseline score, high-impact site, and interaction terms of visit with treatment group and baseline score as explanatory variables. Participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were assigned a change from baseline of 0. Participants with missing data were not explicitly imputed, they were accounted for in the analysis model. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO → GUS group.

GUS was generally well tolerated; safety findings through the final safety follow-up visit (Week 56) were consistent with the established GUS safety profile with no new safety signals identified

Safety Analysis Set	Weeks 0-16		Week 16-56	Week 0-56
	PBO (N=113)	GUS (N=225)	PBO → GUS (N=104)[k]	GUS (N=225)
Mean weeks of follow-up	15.8	15.9	38.5	53.4
Participants with ≥1 AE	45 (39.8%)	85 (37.8%)	56 (53.8%)	138 (61.3%)
AEs leading to discontinuation of study agent	4 (3.5%)	0	1 (1.0%)	4 (1.8%)
Serious AEs	1 (0.9%)	3 (1.3%)	2 (1.9%)	12 (5.3%)
Participants with ≥1 AE of interest				
Infections	23 (20.4%)	50 (22.2%)	42 (40.4%)	85 (37.8%)
Serious infections	1 (0.9%)[l]	0	1 (1.0%)[m]	2 (0.9%)[n]
MACE	0	1 (0.4%)[o,p]	0	4 (1.8%)[o,p]
Malignancy	0	0	0	2 (0.9%)[q]
NMSC	0	0	0	2 (0.9%)[q]
Excluding NMSC	0	0	0	0
VTE	0	0	0	1 (0.4%)[o,r]
Serum-like sickness or anaphylaxis	0	0	0	0
Active tuberculosis	0	0	0	0
Inflammatory bowel disease	0	0	0	0

Participants were counted only once for any given event, regardless of the number of times they experienced the event. AEs were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.1. [k]*For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO → GUS group;* [l]*One participant had pneumonia;* [m]*One participant had appendicitis;* [n]*One participant had a pelvic abscess and one participant had acute osteomyelitis of the cervical spine and sepsis;* [o]*Participants had relevant cardiovascular risk factors;* [p]*During Weeks 0-16, one participant had a cerebrovascular accident; from Weeks 16-56, one participant had a myocardial infarction, one participant had coronary artery occlusion, and one participant had unstable angina;* [q]*Two participants had basal cell carcinoma;* [r]*One participant had bilateral pulmonary embolism.* ***MACE****=major adverse cardiovascular event,* ***NMSC****=non-melanoma skin cancer,* ***VTE****=venous thromboembolism.*

Key Takeaways

At Week 48 in the SPECTREM study, with GUS treatment:

- ~70-80% of participants achieved clear or almost clear skin (IGA 0/1, PASI 90)
- Mean percent improvements in BSA and PASI were >85%
- Over 60% of participants achieved DLQI 0/1 (no effect of PsO on QoL)
- Meaningful improvements in mean PSSD itch (≥4.5 points) and PsAID-12 scores (>3 points) were achieved

No new safety signals were identified

Consistent improvements across clinician-evaluated skin clearance and patient-reported skin/joint outcome measures substantiate GUS efficacy in patients with low BSA, moderate psoriasis with high-impact site involvement

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