SPECTREM: Guselkumab Demonstrates Significant Clearance Across the Most Commonly Presenting Special Sites in Participants with Low BSA Moderate Psoriasis

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Disclosures

ABG: has received research funding and/or receives research/educational grants from Bristol Myers Squibb, Highlights Therapeutics, Janssen, and UCB (all paid to Mount Sinai School of Medicine) and has received honoraria as an advisory board member and consultant for Amgen, AnaptypsBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA).

JK: is a consultant and/or has received honoraria from: AbbVie, Aclaris, Allergan, Almirall, Amgen, Arena, Aristea, Asana, Aurigene, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Escalier, Galapagos, Janssen, MoonLake, Nimbus, Novartis, Pfizer, Sanofi, Sienna, SUN, Target-Derm, UCB, Valeant, Ventyx.

KBG: received research/grant support from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Novartis, and UCB and honoraria for consultation from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Janssen, Novartis, and UCB.

RB: is an advisory board member, consultant, speaker and/or investigator for and received honoraria and/or grants from AbbVie, Alumis, Arcutis, Amgen, Bausch Health, Boston, BMS/Celgene, Dermavant, Eli Lilly, Janssen, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, UCB, VentyxBio, and Xencor; and an employee and shareholder of Innovaderm Research.

JGZ: has nothing to declare.

JFM: is a consultant and/or investigator for AbbVie, Amgen, Astra Zeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte, Janssen, LEO Pharma, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, SUN Pharma, and UCB.

TA, **DC**, **OS**, and **JJ**: are employees and stockholders of Johnson & Johnson.

OC: was an employee of Johnson & Johnson at the time the study was conducted and owns stock in Johnson & Johnson; currently an employee of Apogee Therapeutics Inc.

Background

SPECTREM is an ongoing phase 3b, multicenter, randomized, double-blind, placebo (PBO)-controlled study evaluating the efficacy and safety of guselkumab (GUS) in participants with low body surface area (BSA), moderate plaque psoriasis (PsO) involving ≥1 high-impact site

Patients with low BSA PsO are underrepresented in clinical studies or undertreated despite being candidates for systemic treatment[1-3]

SPECTREM was intentionally designed to address the undertreatment of patients with low BSA PsO involving high-impact sites. At baseline, 18.0% of participants had 1 high-impact site involved, 34.3% had 2, and 47.6% had ≥3.

[1]Blauvelt A, et. al. *J Psoriasis Psoriatic Arthritis*. 2023;8:100-6. [2]Golbari NM, et. al. *J Eur Acad Dermatol Venereol*. 2021;35:417-21. [3]Strober B, et. al. *J Am Acad Dermatol*. 2019;82:117-22.

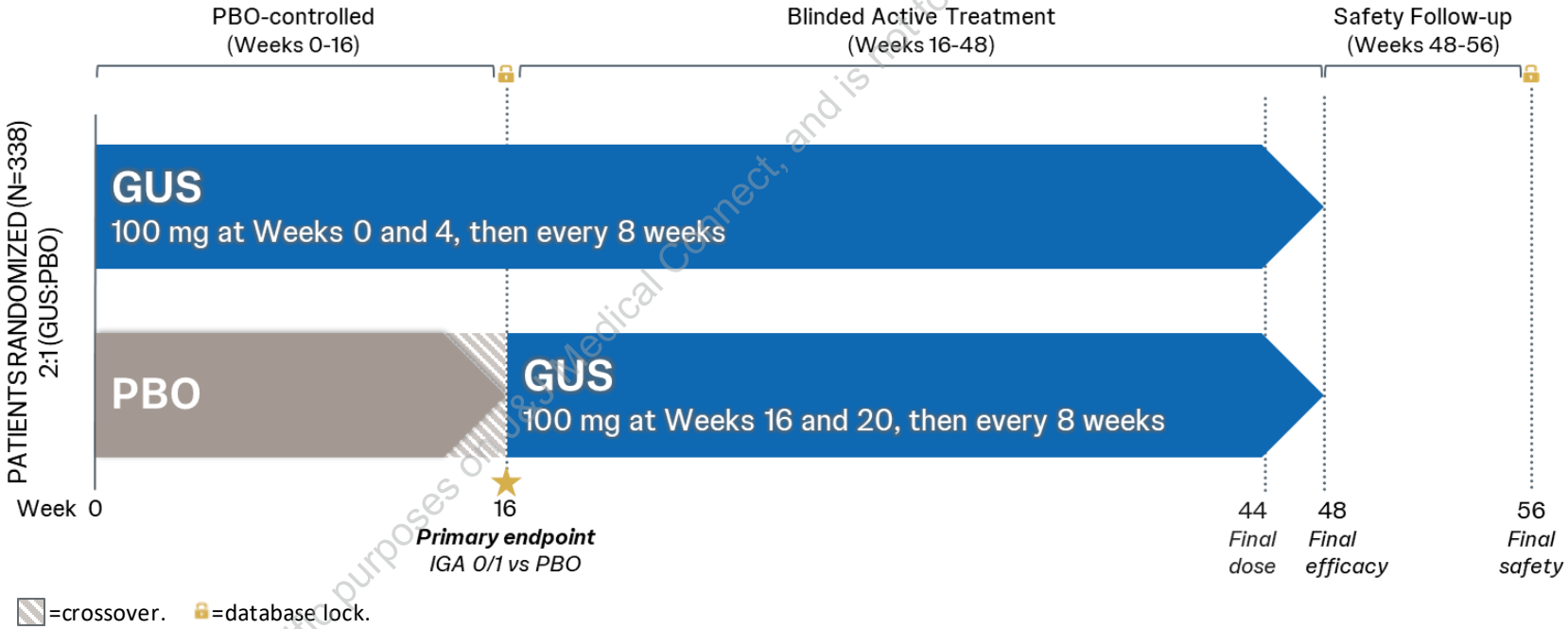
Objectives

To evaluate efficacy of GUS vs PBO at Week 16 using:

- **Site-specific Investigator's Global Assessment (IGA)**
  - **Scalp-specific IGA (ss-IGA)**
  - **Facial IGA (f-IGA)**
  - **Intertriginous IGA (i-IGA)**
  - **Static Physician's Global Assessment of Genitalia (sPGA-G)**
- **Psoriasis Symptoms and Signs Diary (PSSD)**
- **Dermatology Life Quality Index (DLQI)**

Methods

Key Inclusion Criteria
- IGA=3
- BSA=2-15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact site with at least moderate severity (scalp, face, intertriginous, genital)



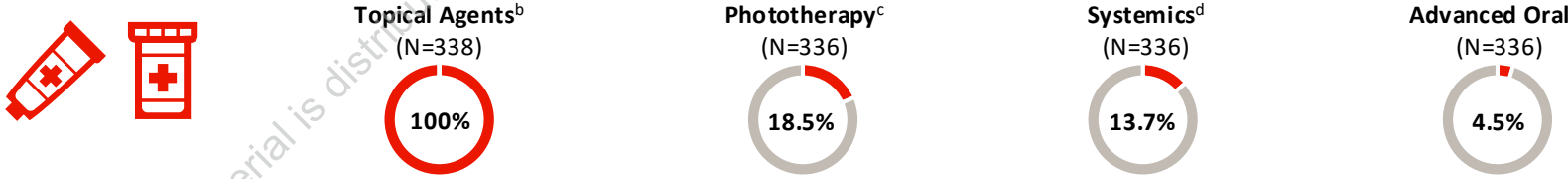
A total of 338 participants were randomized to receive GUS (N=225) or PBO (N=113)

Endpoints presented at Week 16 include:

- Proportions of participants achieving IGA 0/1, ss-IGA 0/1, f-IGA 0/1, i-IGA 0/1, sPGA-G 0/1
- Mean change from baseline in PSSD total symptoms score, proportion of participants achieving PSSD total symptoms score of 0, ≥4-point improvement in PSSD itch score, and DLQI of 0 or 0/1

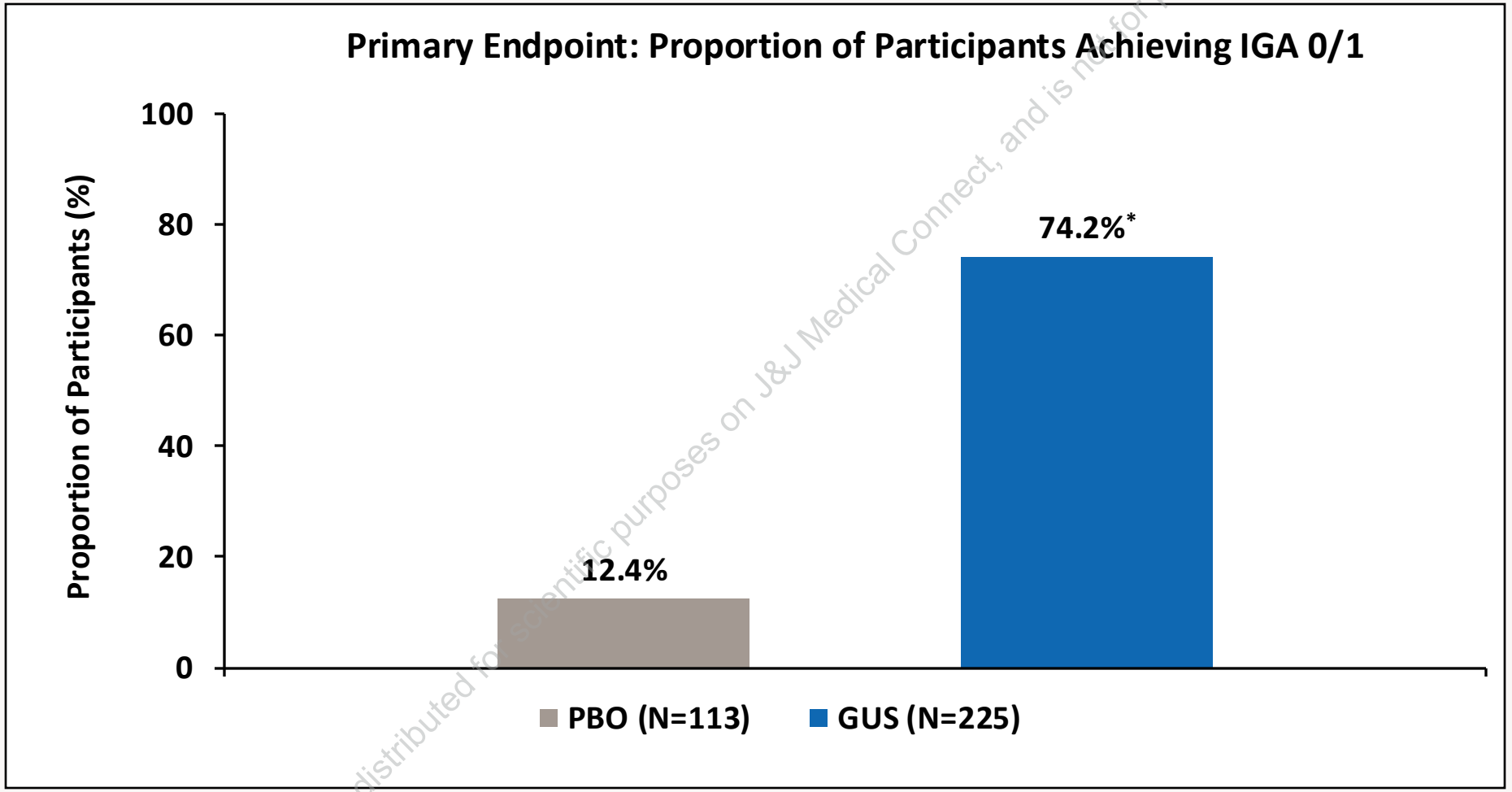
Baseline demographics and disease characteristics were generally comparable between the PBO and GUS groups

	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	50%	52%	51%
White	74%	74%	74%
BMI, kg/m^2	31.0 (7.5)	30.9 (7.5)	30.9 (7.5)
Characteristics			
PsO disease duration, yrs	14.0 (11.9)	18.4 (14.9)	16.9 (14.1)
IGA			
Moderate (3)	100%	99.6%	99.7%
Severe (4)	0	0.4%[a]	0.3%
BSA, %	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)
Site-specific assessment score ≥3			
Scalp	67%	68%	68%
Face	37%	40%	39%
Intertriginous	46%	49%	48%
Genital	35%	36%	36%
Patient-reported outcomes			
PSSD symptoms score (0-100)[b]	54.9 (22.0)	53.3 (23.7)	53.8 (23.2)
PSSD itch score (0-10)[b]	6.8 (2.0)	6.7 (2.2)	6.8 (2.2)
Previous medication use			



Data shown are mean (SD), unless otherwise indicated. [a]Inclusion criteria deviation; [b]Topical, anthralin, keratolytics, tar; [c]PUVA, UVB; [d]PUVA, methotrexate, cyclosporine, acitretin; [e]Apremilast, deucravacitinib. **BMI**=body mass index; **PASI**=Psoriasis Area and Severity Index; **PUVA**=psoralen plus ultraviolet A; **SD**=standard deviation; **UVB**=ultraviolet B.

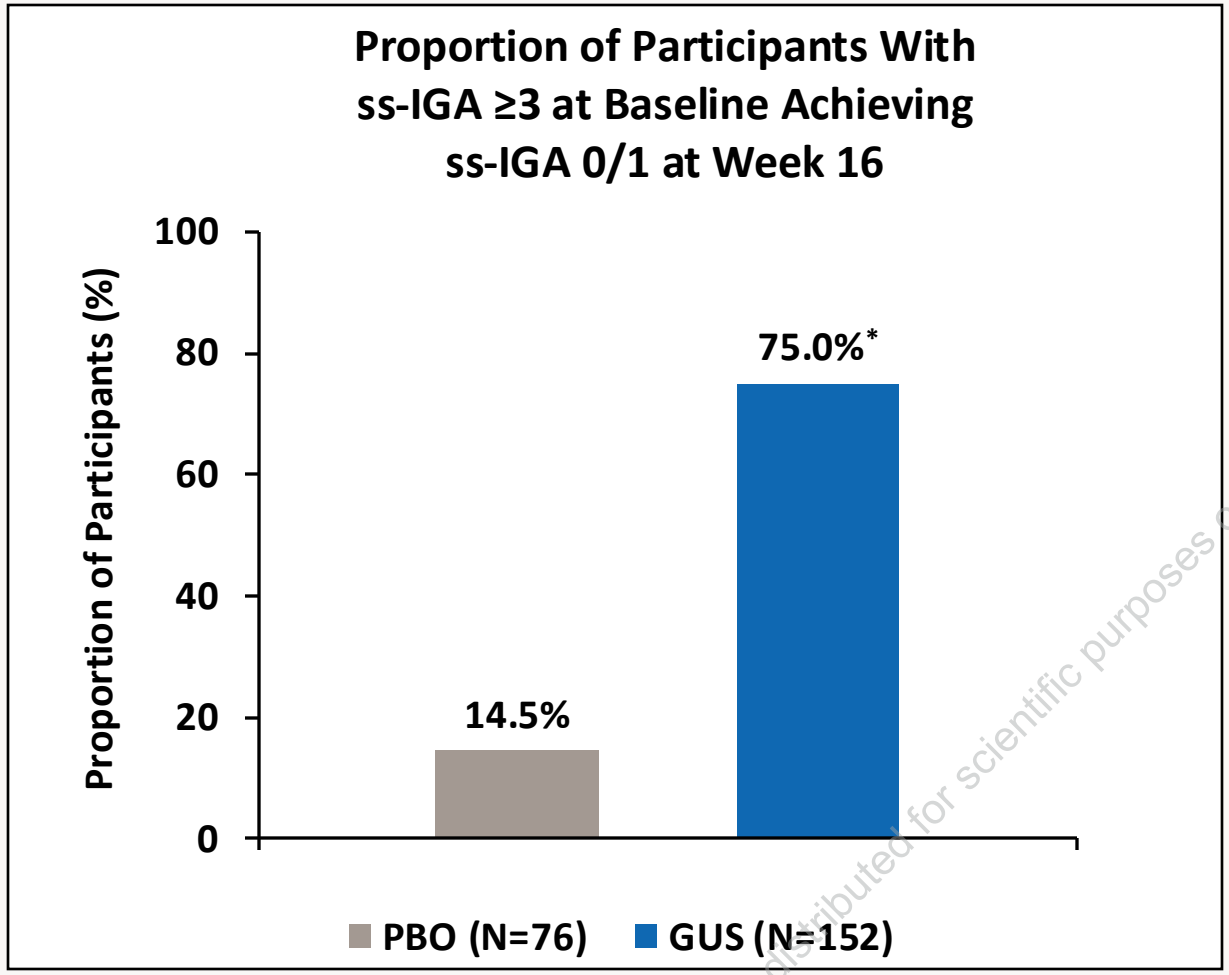
A significantly greater proportion of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16



*p<0.001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel (CMH) test stratified by high-impact site (scalp, face, intertriginous, genital).
Nonresponder imputation (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.

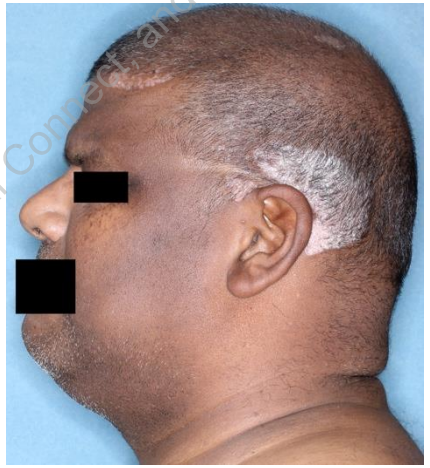
75% of GUS-randomized participants achieved ss-IGA 0/1 at Week 16

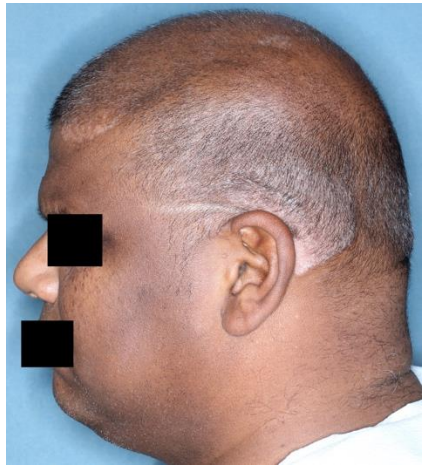
Scalp

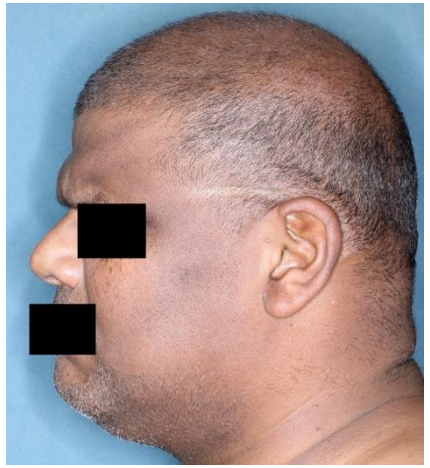


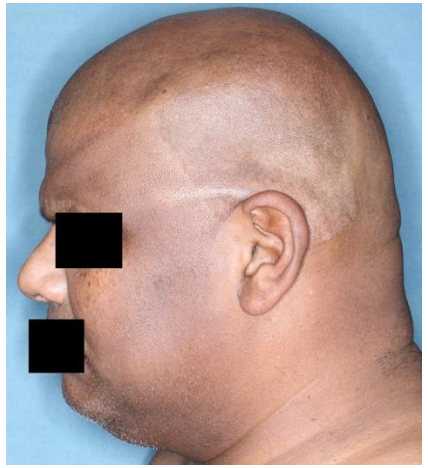
*p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

GUS-randomized participant with ss-IGA ≥3 at baseline who achieved ss-IGA 0/1 at Week 16


Week 0: ss-IGA=3

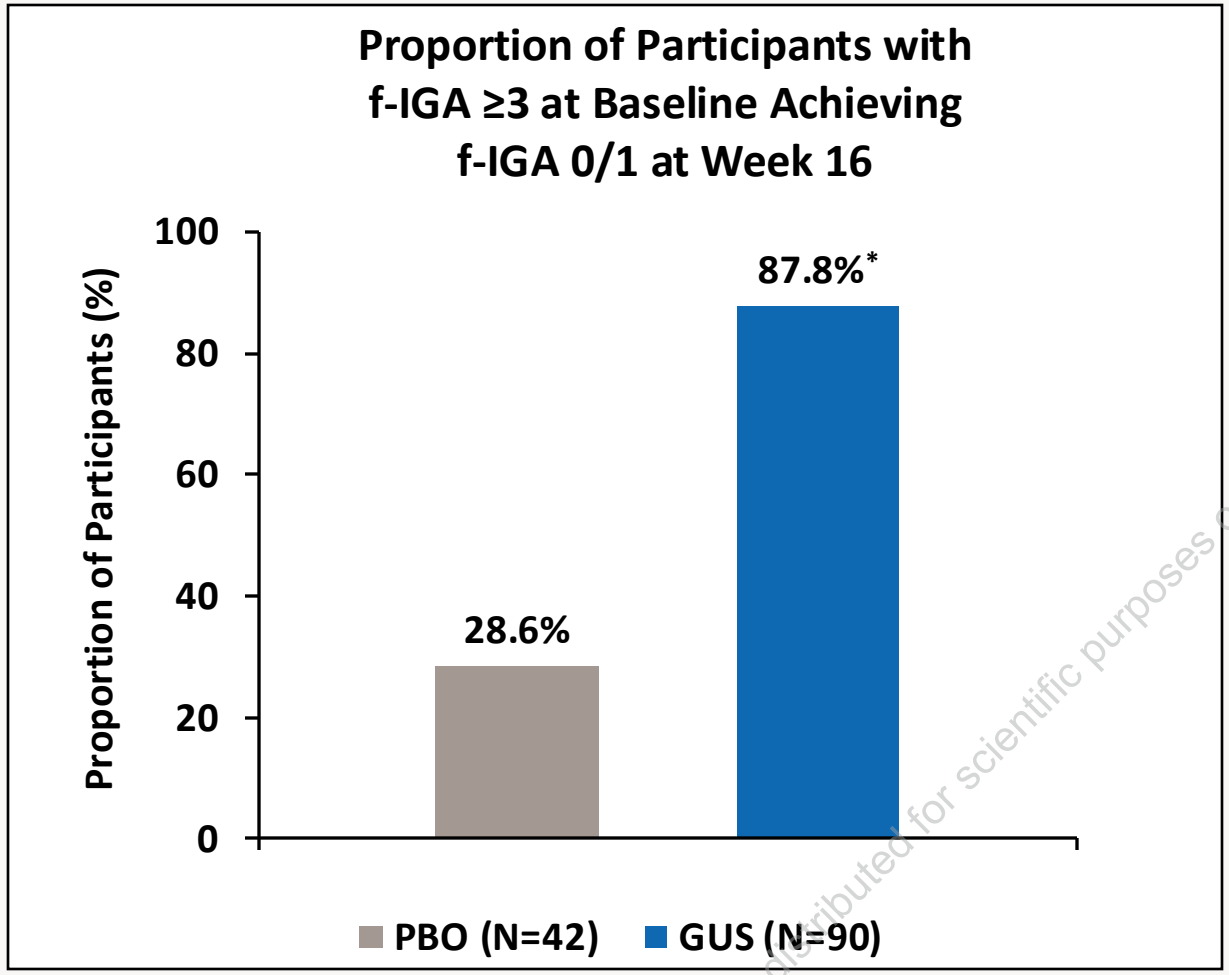

Week 4: ss-IGA=2


Week 12: ss-IGA=1


Week 16: ss-IGA=0

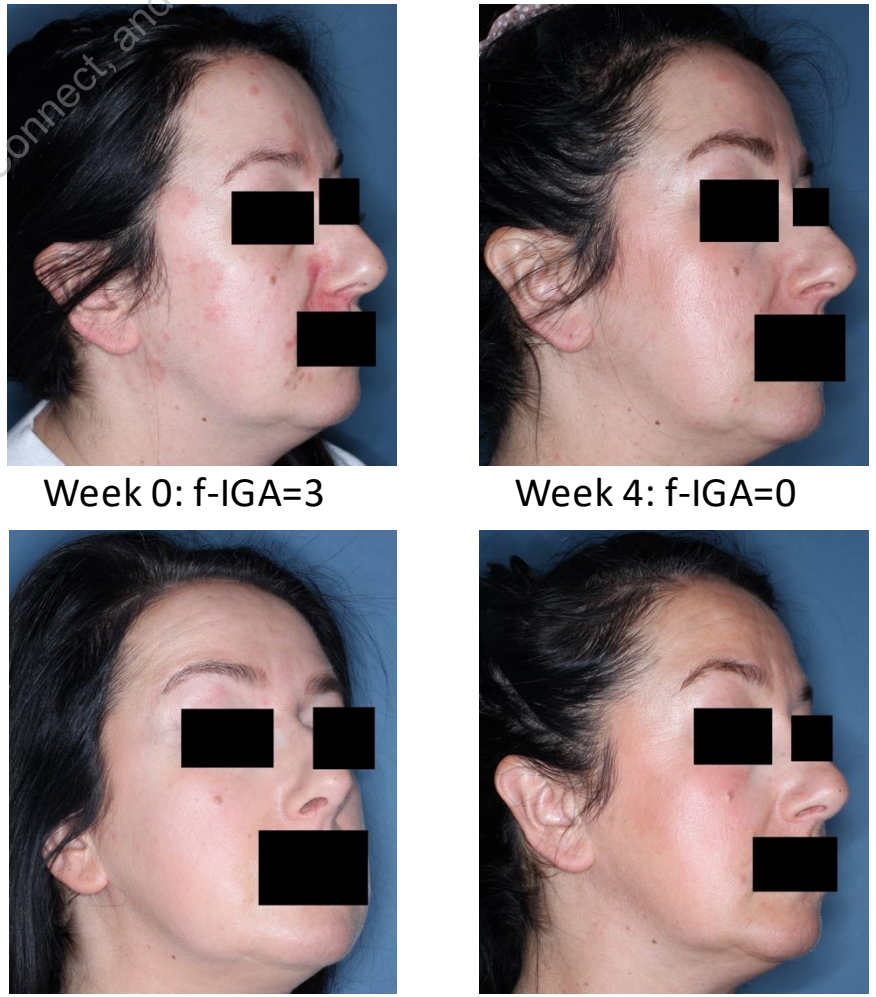
88% of GUS-randomized participants achieved f-IGA 0/1 at Week 16

Face



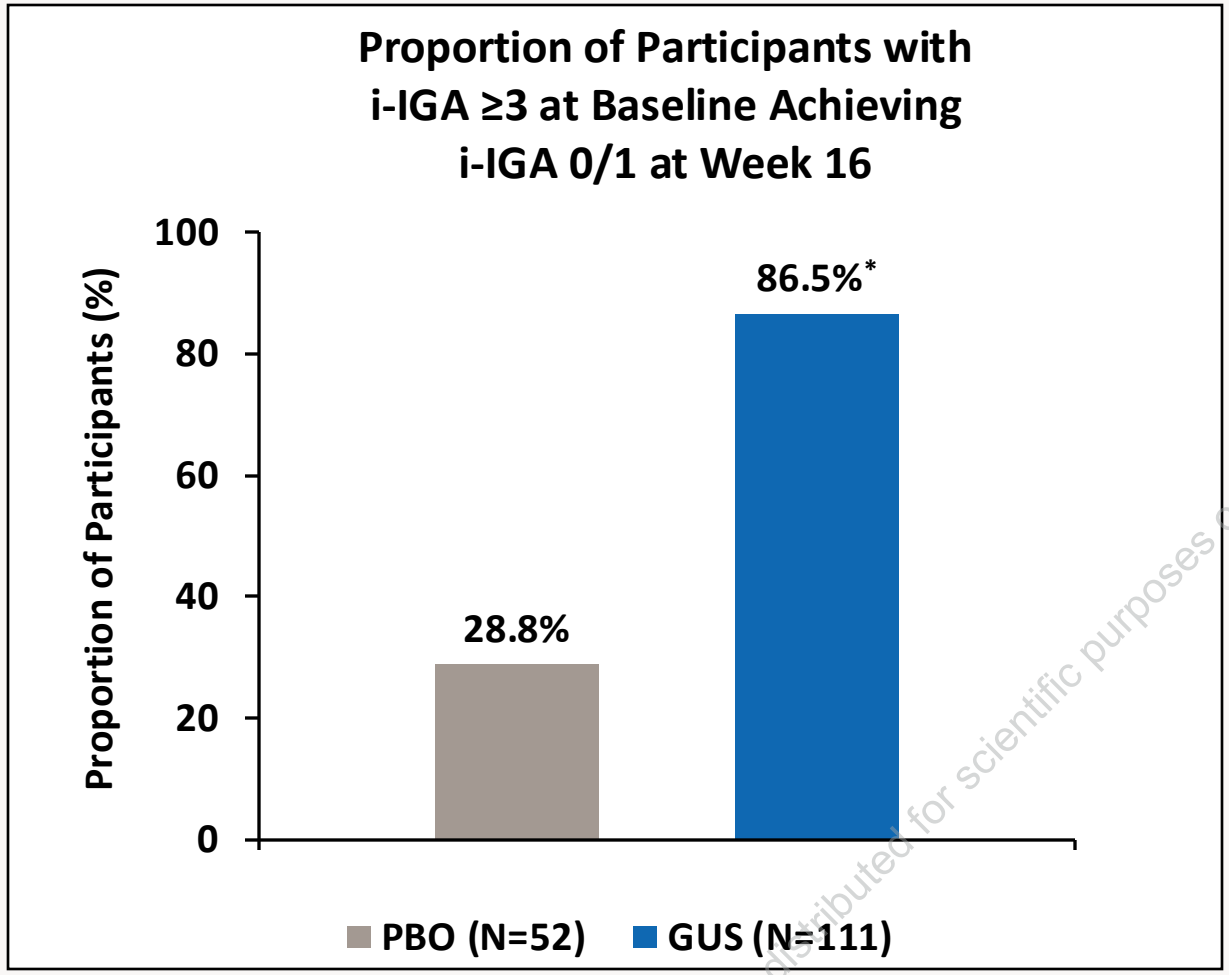
*p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

GUS-randomized participant with f-IGA ≥3 at baseline who achieved f-IGA 0/1 at Week 16



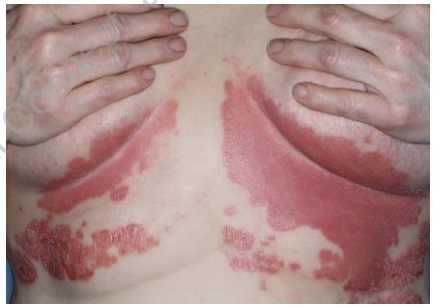
86% of GUS-randomized participants achieved i-IGA 0/1 at Week 16

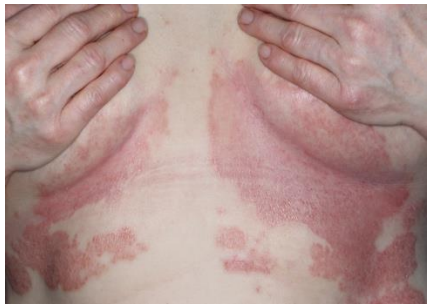
Intertriginous

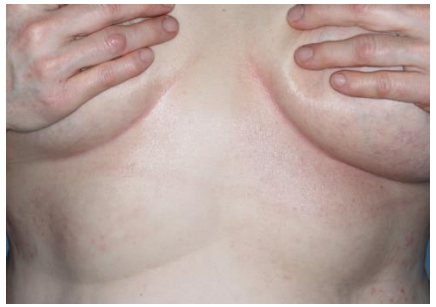


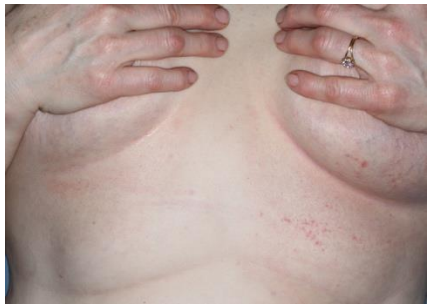
*p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

GUS-randomized participant with i-IGA ≥3 at baseline who achieved i-IGA 0/1 at Week 16


Week 0: i-IGA=3

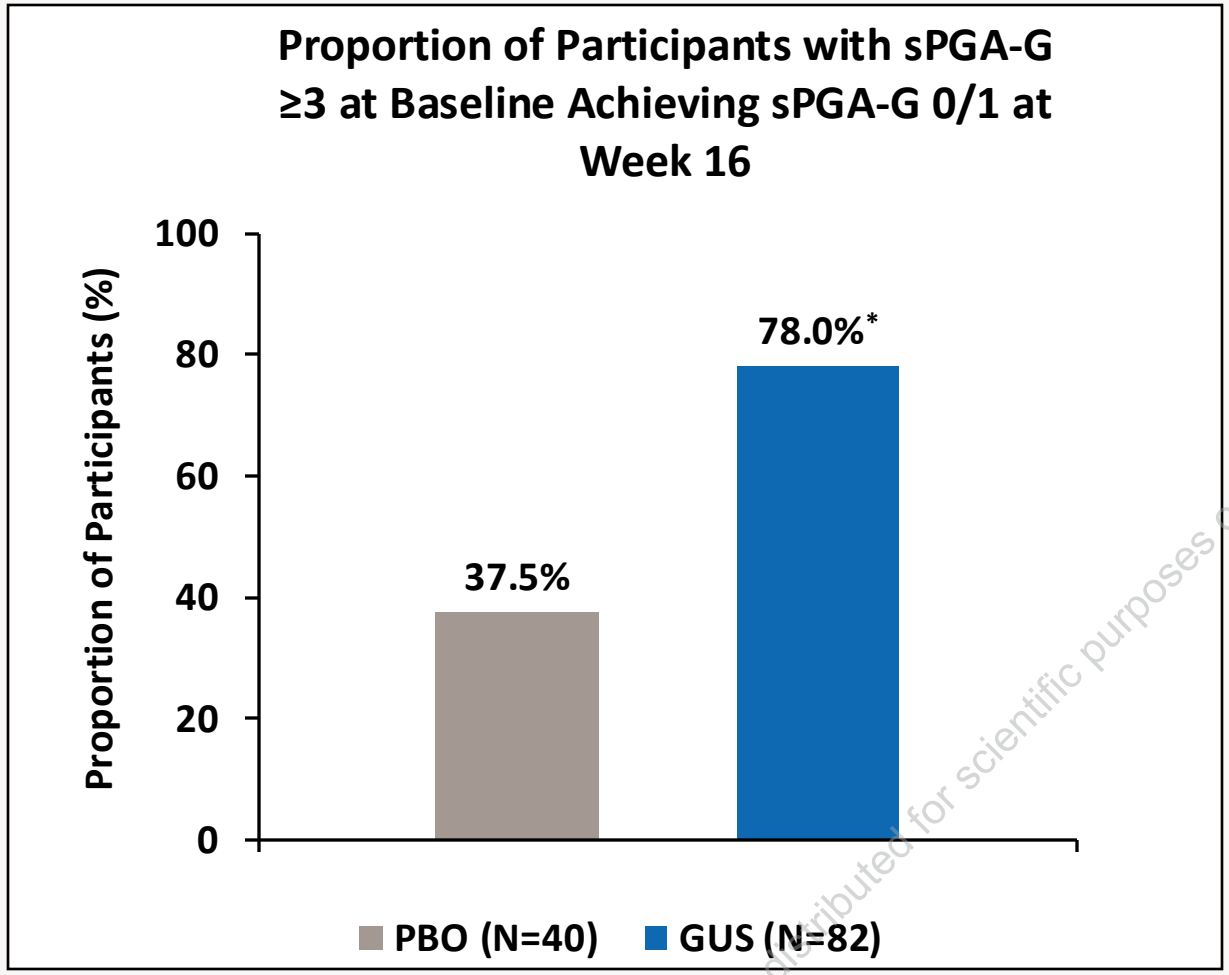

Week 4: i-IGA=3


Week 12: i-IGA=0


Week 16: i-IGA=0

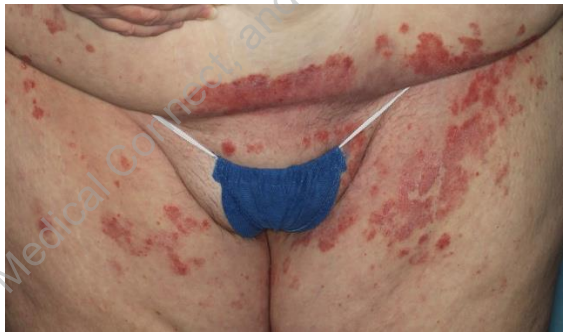
78% of GUS-randomized participants achieved sPGA-G 0/1 at Week 16

Genital

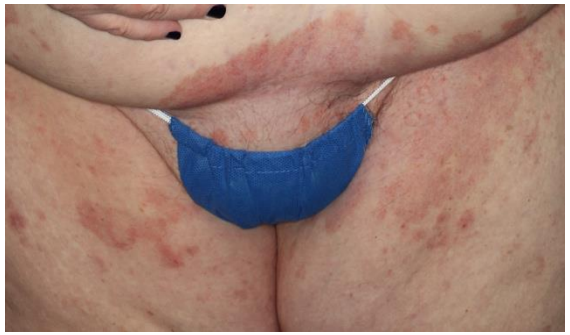


*p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

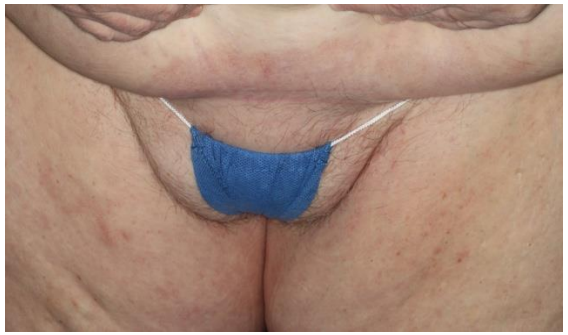
GUS-randomized participant with sPGA-G ≥3 at baseline who achieved sPGA-G 0/1 at Week 16



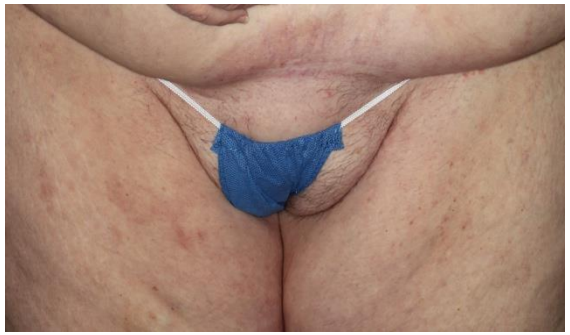
Week 0: sPGA-G=3
Week 0: I-IGA=3



Week 4: sPGA-G=0
Week 4: I-IGA=2

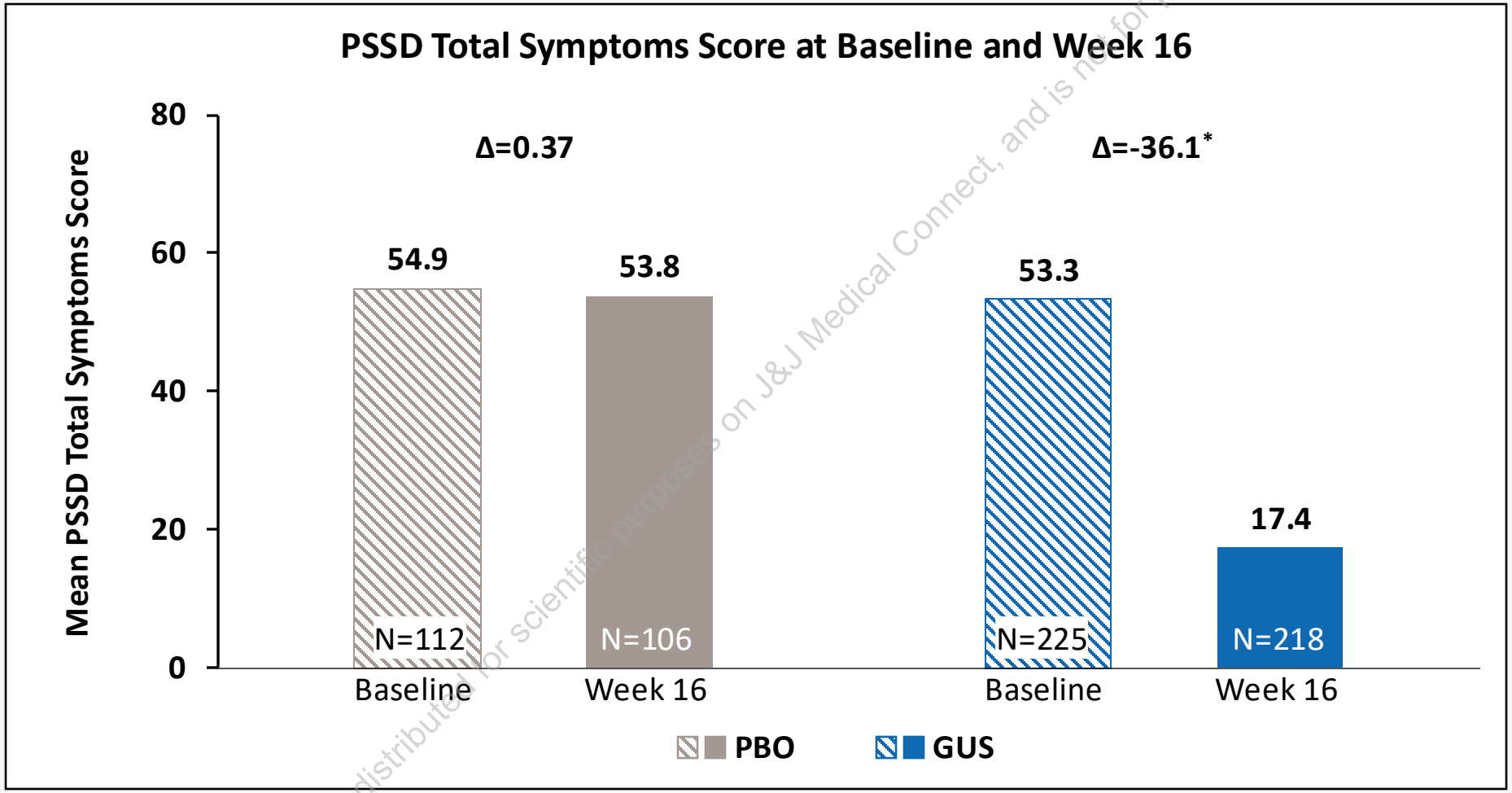


Week 12: sPGA-G=0
Week 12: I-IGA=1



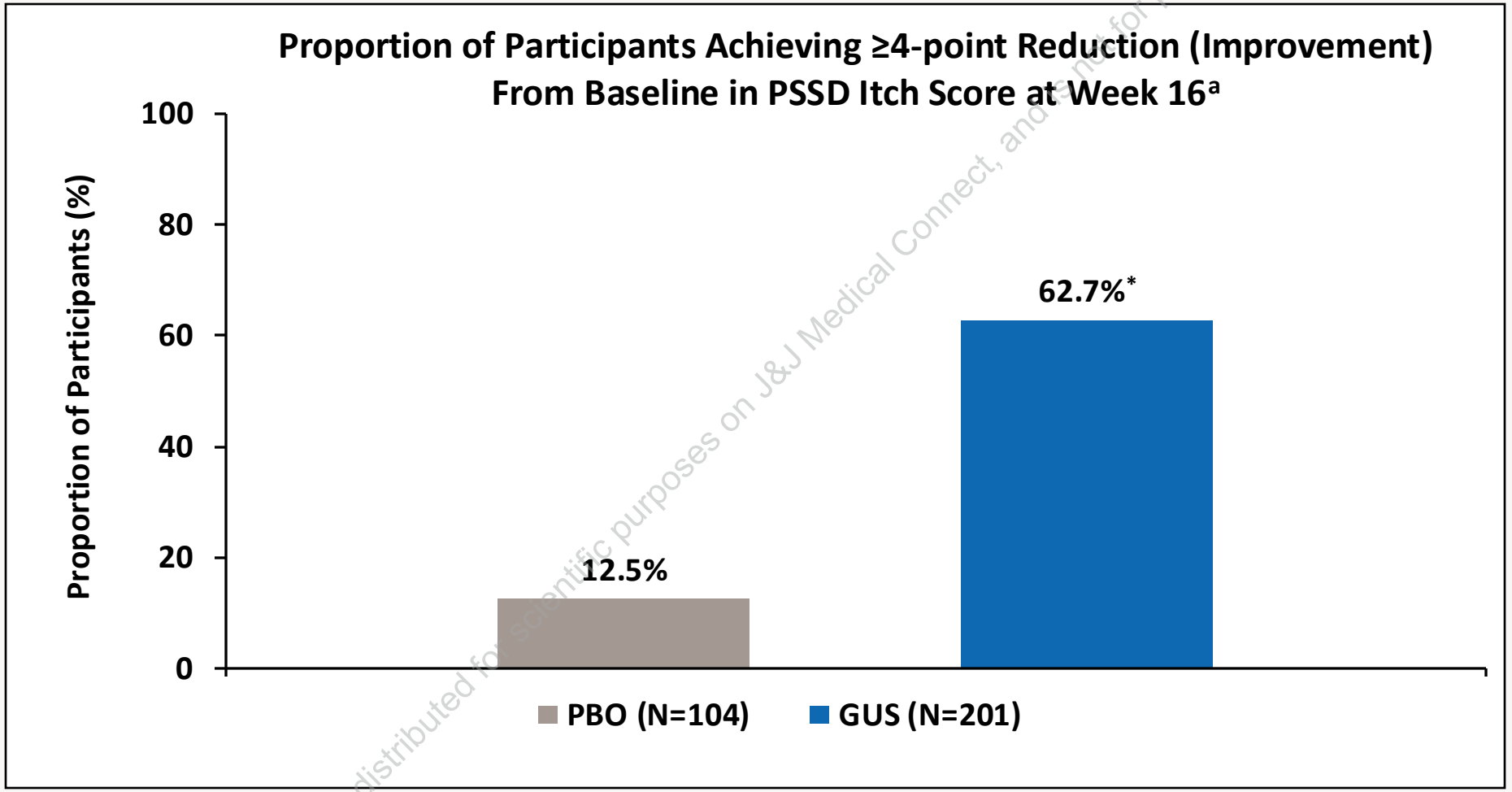
Week 16: sPGA-G=0
Week 16: I-IGA=1

GUS-randomized participants achieved significantly greater mean change from baseline in the PSSD total symptoms score vs PBO-randomized participants



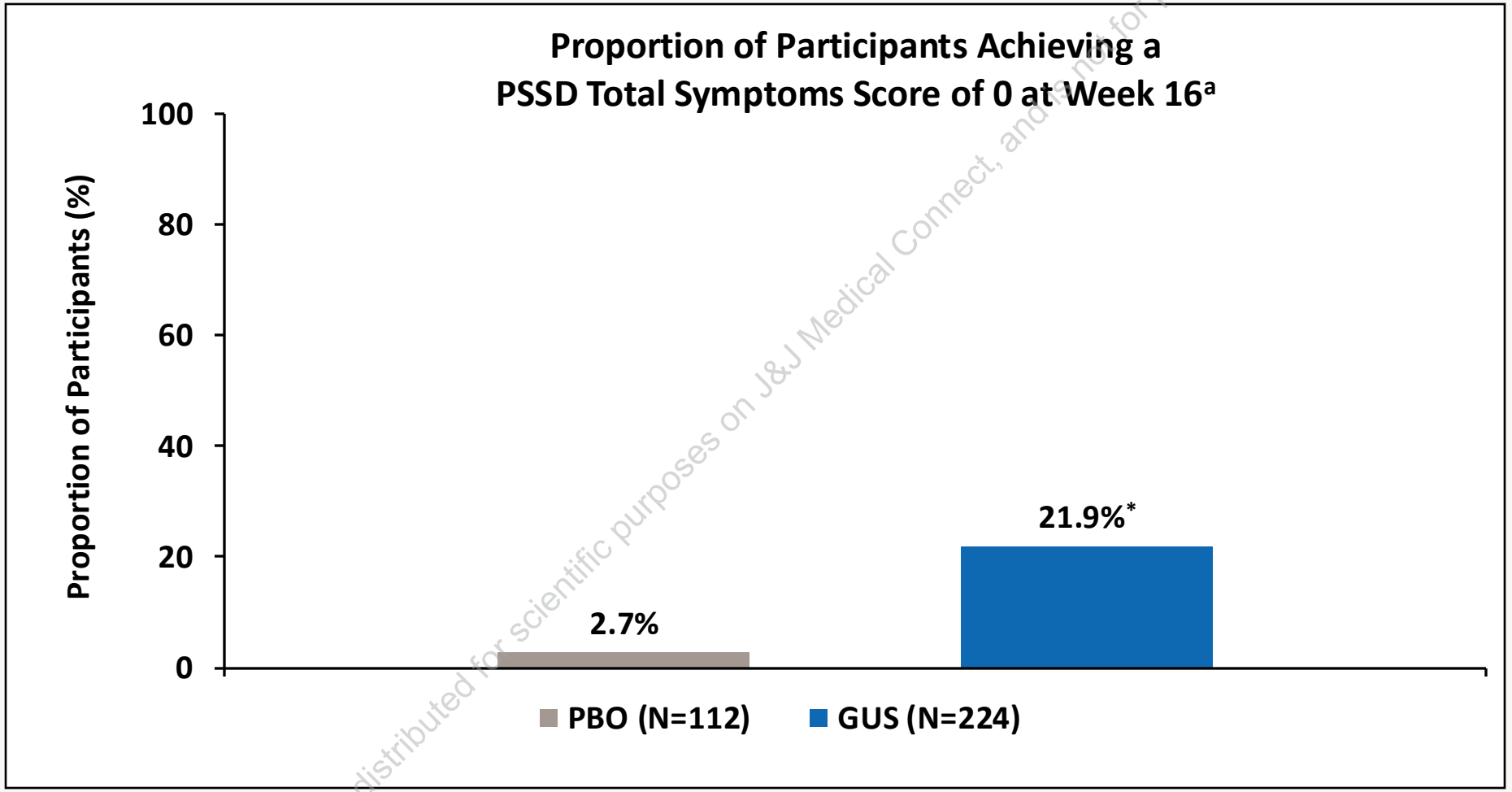
*p<0.001 GUS vs PBO; p-value is based on the mixed-effect model for repeated measures (MMRM) with explanatory variables of treatment group, visit, baseline score, high-impact site, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. Δ=Least-squares mean change from baseline; a negative change indicates an improvement, and a positive change indicates worsening of disease. When participants discontinued study agent due to lack of efficacy, worsening of PsO or use of a prohibited PsO treatment, zero change was assigned from that point onward. Missing data were handled by MMRM under missing at random assumption.

A significantly greater proportion of GUS-randomized participants achieved ≥4-point reduction (improvement) from baseline in PSSD itch score vs PBO-randomized participants



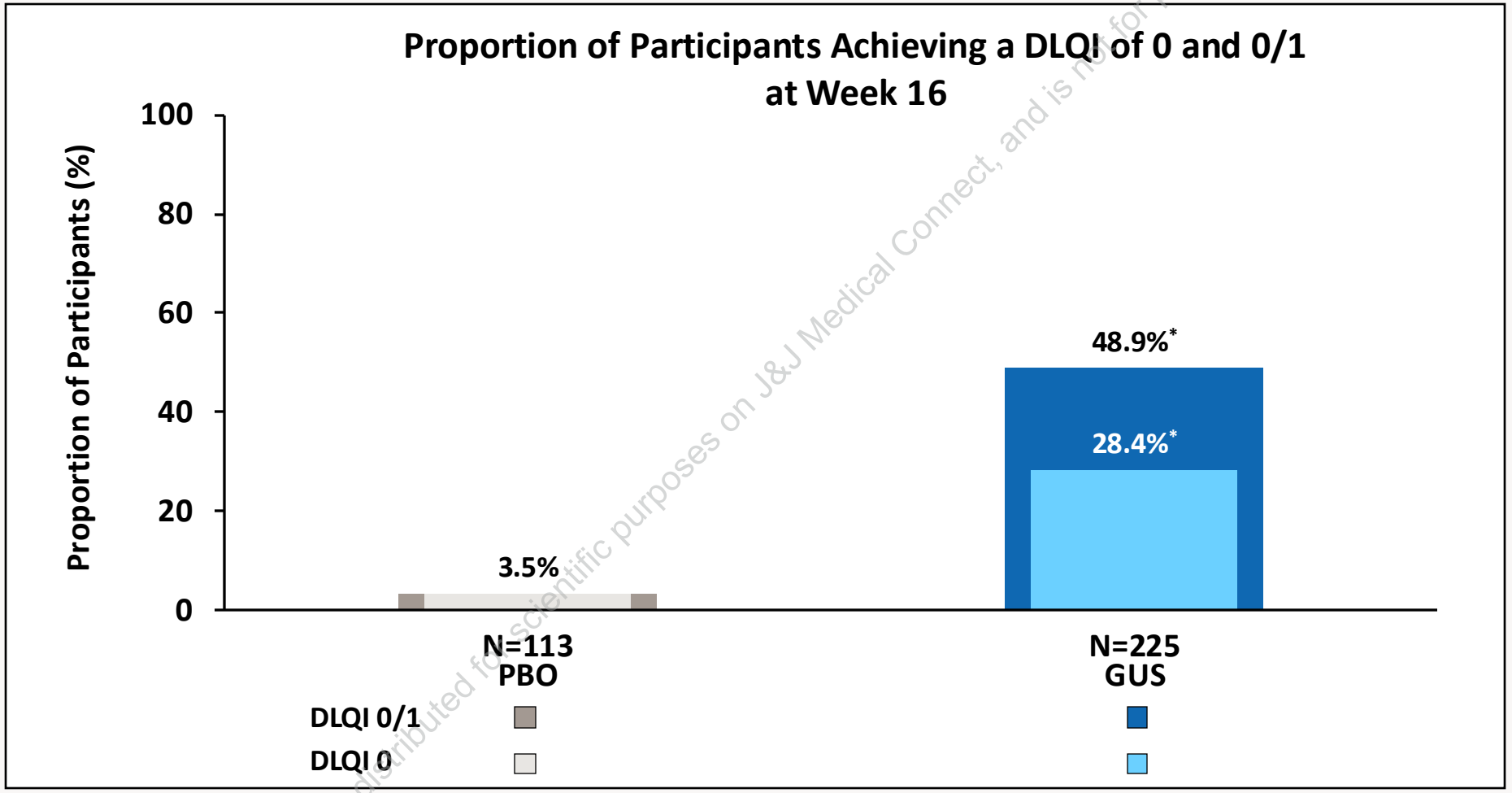
*p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). [a]Among participants with a PSSD itch score ≥4 at baseline. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

A significantly greater proportion of GUS-randomized participants achieved a PSSD total symptoms score of 0 vs PBO-randomized participants



*p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). [a]Among participants with a PSSD symptoms score >0 at baseline. 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.

A greater proportion of GUS-randomized participants achieved DLQI of 0 and 0/1



*nominal p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). 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.

Key Takeaways

- **Guselkumab is highly effective in participants with low BSA, moderate plaque psoriasis with ≥1 high-impact site involvement through Week 16**
- **The majority of participants achieved significant improvement at high-impact body sites after just 3 doses of guselkumab, substantiating its efficacy across a broad range of patients**