SPECTREM: Guselkumab Demonstrates Consistent Significant Clearance Across the Full Range of Low Body Surface Area, Moderate Psoriasis With Special Sites Involvement

L Stein Gold,[1] B Strober,[2,3] AW Armstrong,[4] T Alkousakis,[5] KA Papp,[6,7] R Langley,[8] O Choi,[5] D Chan,[5] J Jeyarajah,[5] V Groysman,[9] MG Lebwohl[10]

[1]Henry Ford Medical Center, West Bloomfield, MI, USA; [2]Yale University, New Haven, CT, USA; [3]Central Connecticut Dermatology Research, Cromwell, CT, USA; [4]University of California Los Angeles, Los Angeles, CA, USA; [5]Johnson & Johnson, Horsham and Spring House, PA, USA; [6]Alliance Clinical Trials and Probity Medical Research, Waterloo, ON, Canada; [7]Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada; [8]Division of Dermatology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; [9]Cahaba Dermatology and Skin Health Center, LLC, Birmingham, AL, USA; [10]Icahn School of Medicine at Mount Sinai, New York, NY, USA

This poster was sponsored by Johnson & Johnson, Horsham, PA, USA.
Presented at: AAD Annual Meeting; March 7-11, 2025; Orlando, Florida.

Disclosures

LSG: is an investigator/advisor and/or speaker for AbbVie, Amgen, Arctis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, and UCB.
BS: served as a consultant (honoraria) and/or speaker and/or investigator for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Cara, Connect, CorEvitas Psoriasis Registry, Dermavant, Dermira, Eli Lilly, EPI, Evelo, Immunic, Incyte, Janssen, LEO Pharma, Maruho, Meiji Seika, Mindera, Novartis, Ono, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma, UCB, Union, Ventyxbio, and vTv; served as Co-Scientific Director (consulting fee) of CorEvitas (formerly Corrona) Psoriasis Registry and Editor-in-Chief (honorarium) of Journal of Psoriasis and Psoriatic Arthritis.
AWA: research investigator and/or consultant to AbbVie, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, Janssen, KHK, LEO Pharma, Modernizing Medicine, Novartis, Ortho Dermatologics, Regeneron, Sanofi, Sun Pharma, and UCB.
KAP: clinical research grants, honoraria, and/or consultant, scientific advisor, investigator, speaker, and/or medical officer: AbbVie, Acelyrin, Akros, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, Dermavant, Dermira, Dice Pharmaceuticals, Dice Therapeutics, Eli Lilly, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, Tarsus Pharmaceuticals, Inc., UCB, and Zai Lab Co., Ltd.
RL: has served and has received compensation in the form of grant funding and/or honoraria, as principal investigator for and is on the scientific advisory board or served as a speaker for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sun Pharma, and UCB.
VG: has received clinical research grants, honoraria, and/or served as a consultant, investigator, speaker for: AbbVie, Amgen, Arcutis, Bristol Myers, Dermavant, Dice Pharmaceuticals, Dice Therapeutics, Eli Lilly, Evelo Biosciences, Galderma, Incyte, Janssen, LEO Pharma, Nimbus Therapeutics, Novartis, Pfizer, Sanofi-Aventis/Genzyme, Sun Pharma, and Takeda.
MGL: is an employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Janssen, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, AltruBio Inc., Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica.
TA, **DC,** 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 who may be more effectively treated with systemic therapies are underrepresented in clinical studies

SPECTREM was intentionally designed to address the undertreatment of patients with low BSA PsO involving high-impact sites

Objectives

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

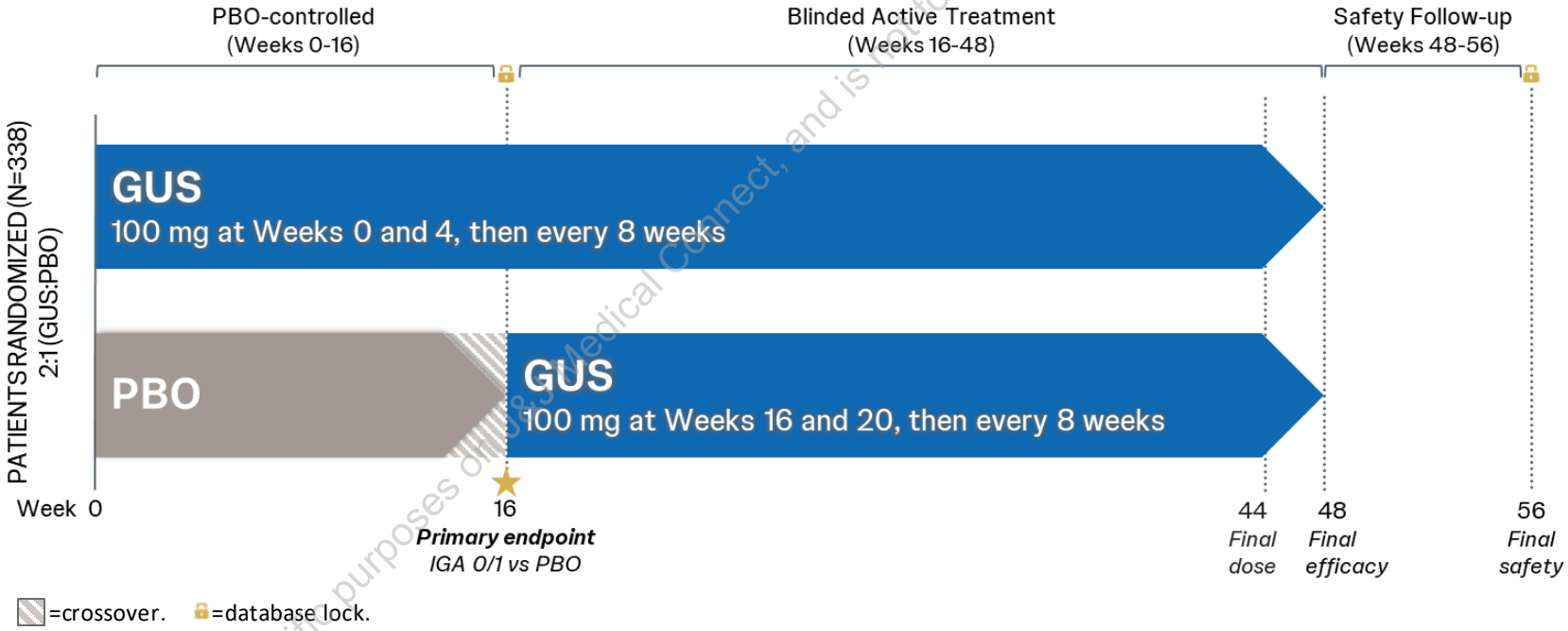
- **Investigator's Global Assessment (IGA)**
- **Psoriasis Area and Severity Index (PASI)**
- **Body surface area (BSA)**

To evaluate safety in SPECTREM participants through Week 16:

- **Adverse events (AEs)**
- **Serious adverse events (SAEs)**

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:

- Primary endpoint: proportion of participants achieving IGA 0/1
- Key major secondary endpoints:
  - Proportion of participants achieving PASI 90, IGA 0, and PASI 100
  - Mean percent improvements from baseline in BSA and PASI

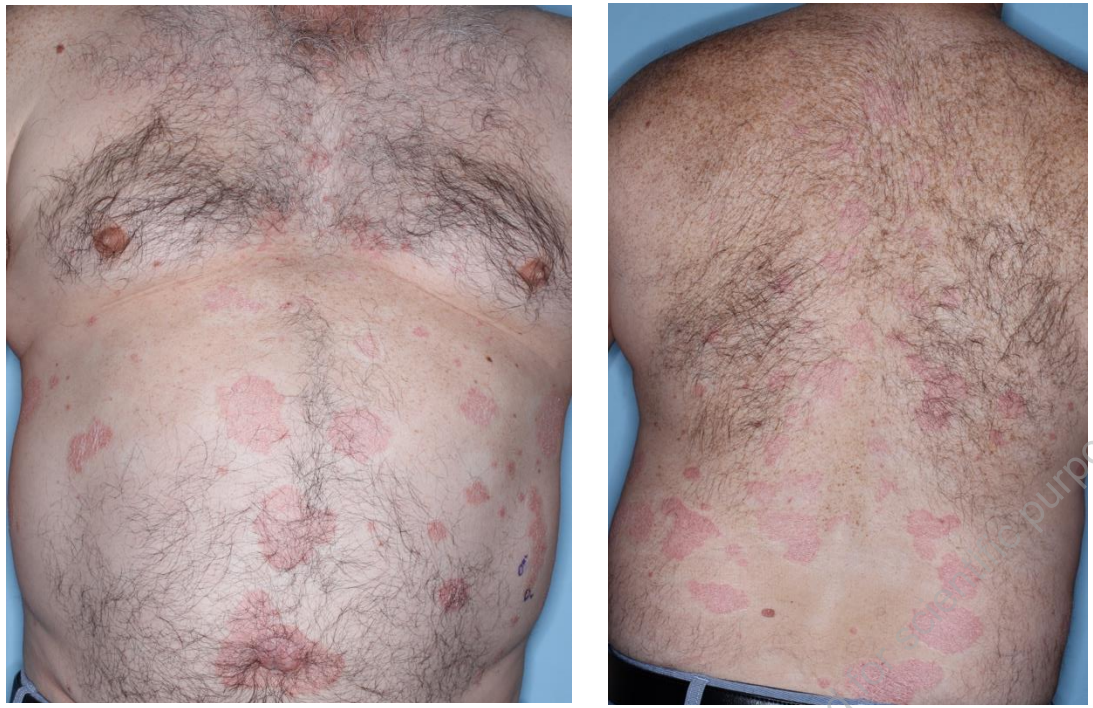
Baseline demographics and disease characteristics were generally comparable between the PBO and GUS groups

	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	57 (50.4%)	116 (51.6%)	173 (51.2%)
White	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)	113 (100%)	224 (99.6%)[a]	337 (99.7%)
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)
Previous medication use			
Topical agents[b]	113 (100%)	225 (100%)	338 (100%)
Phototherapy[c,d]	16 (14.3%)	46 (20.5%)	62 (18.5%)
Conventional systemics[c,e]	15 (13.4%)	31 (13.8%)	46 (13.7%)
Advanced orals[c,f]	4 (3.6%)	11 (4.9%)	15 (4.5%)

Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; [b]Topical, anthralin, keratolytics, tar; [c]PBO N=112, GUS N=224, Total N=336; [d]PUVA, UVB; [e]PUVA, methotrexate, cyclosporine, acitretin; [f]Apremilast, deucravacitinib. **BMI**=body mass index; **PUVA**=psoralen plus ultraviolet A; **SD**=standard deviation; **UVB**=ultraviolet B.

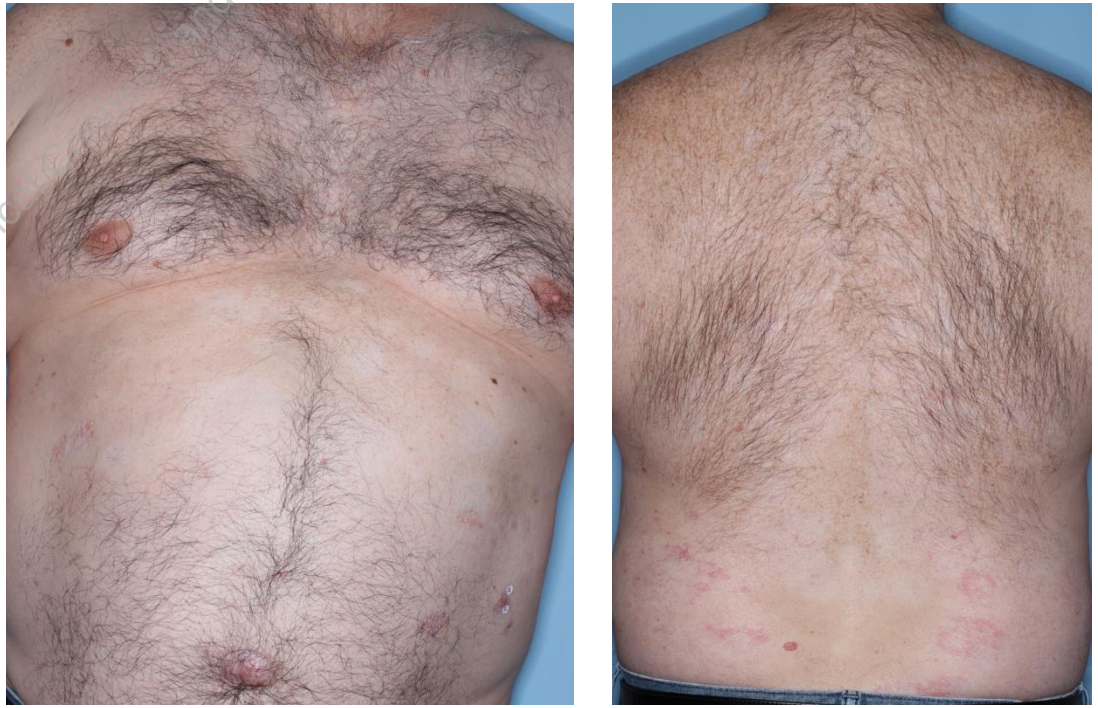
A GUS-randomized participant who achieved the primary endpoint (IGA 0/1) at Week 16

Week 0



IGA: 3, BSA: 12.0%, PASI: 12.0

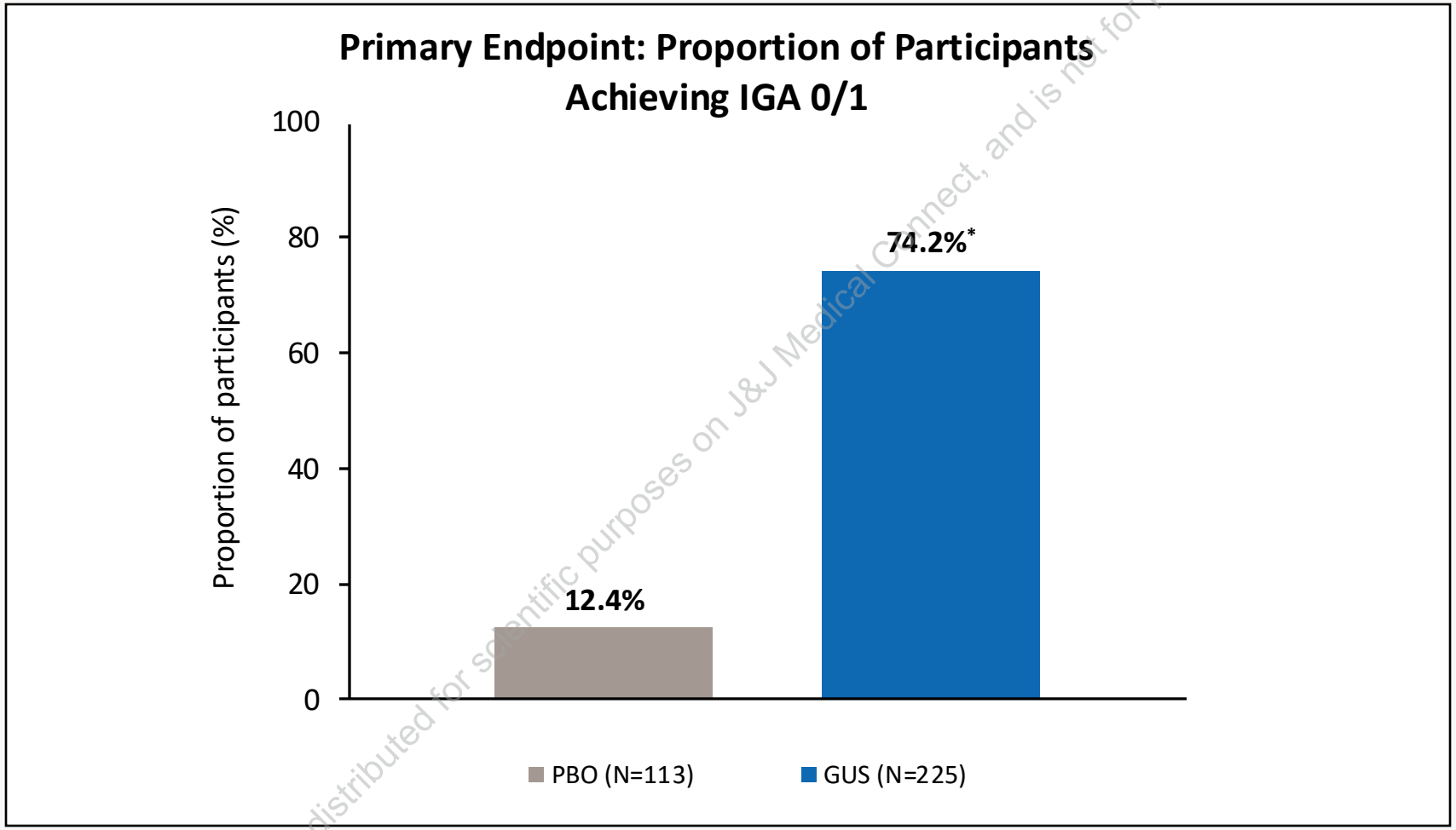
Week 16



IGA: 1, BSA: 2.0%, PASI: 1.0

BSA Improvement: 83.3%
PASI Improvement: 91.7%

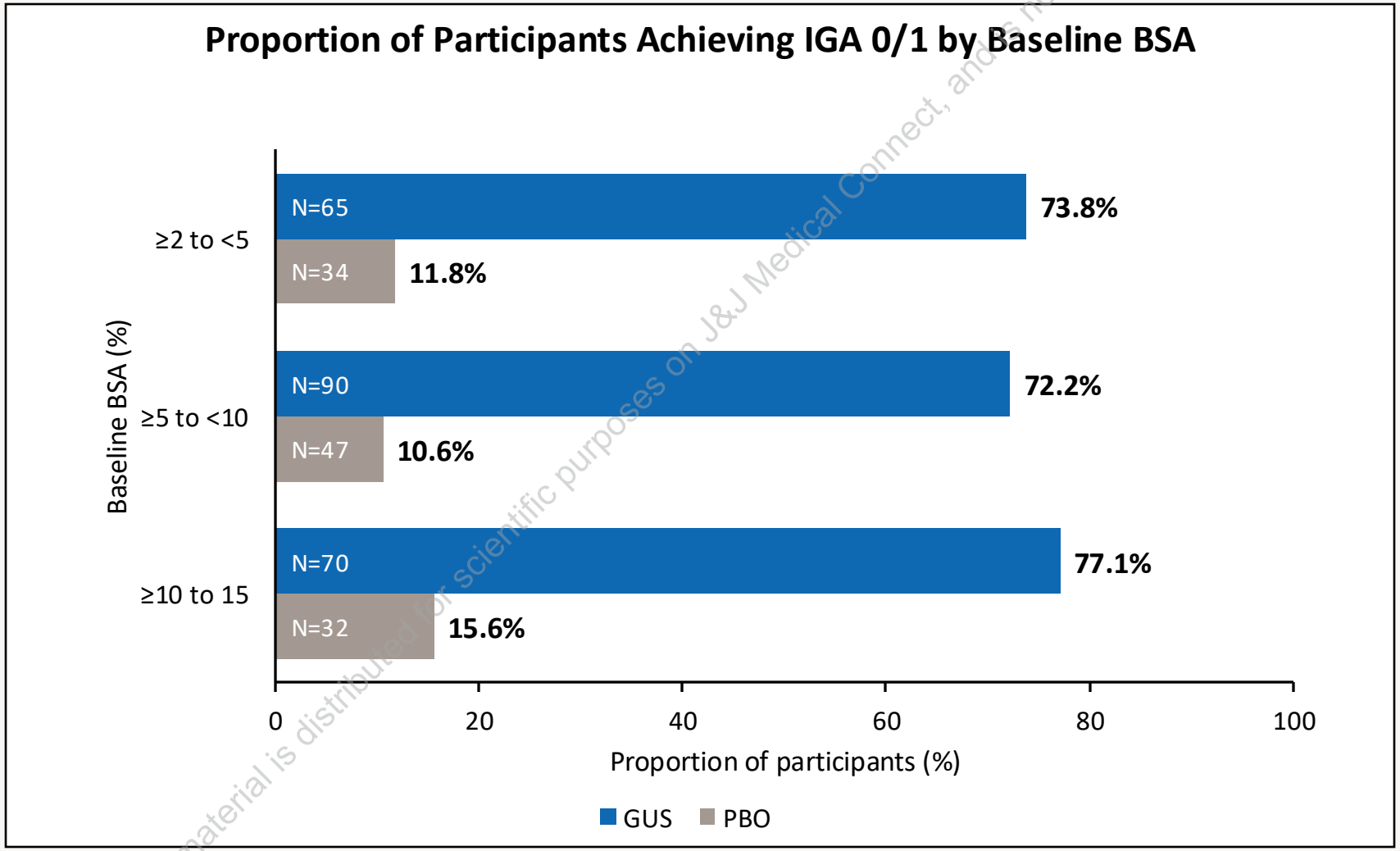
A significantly greater proportion of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16



*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.

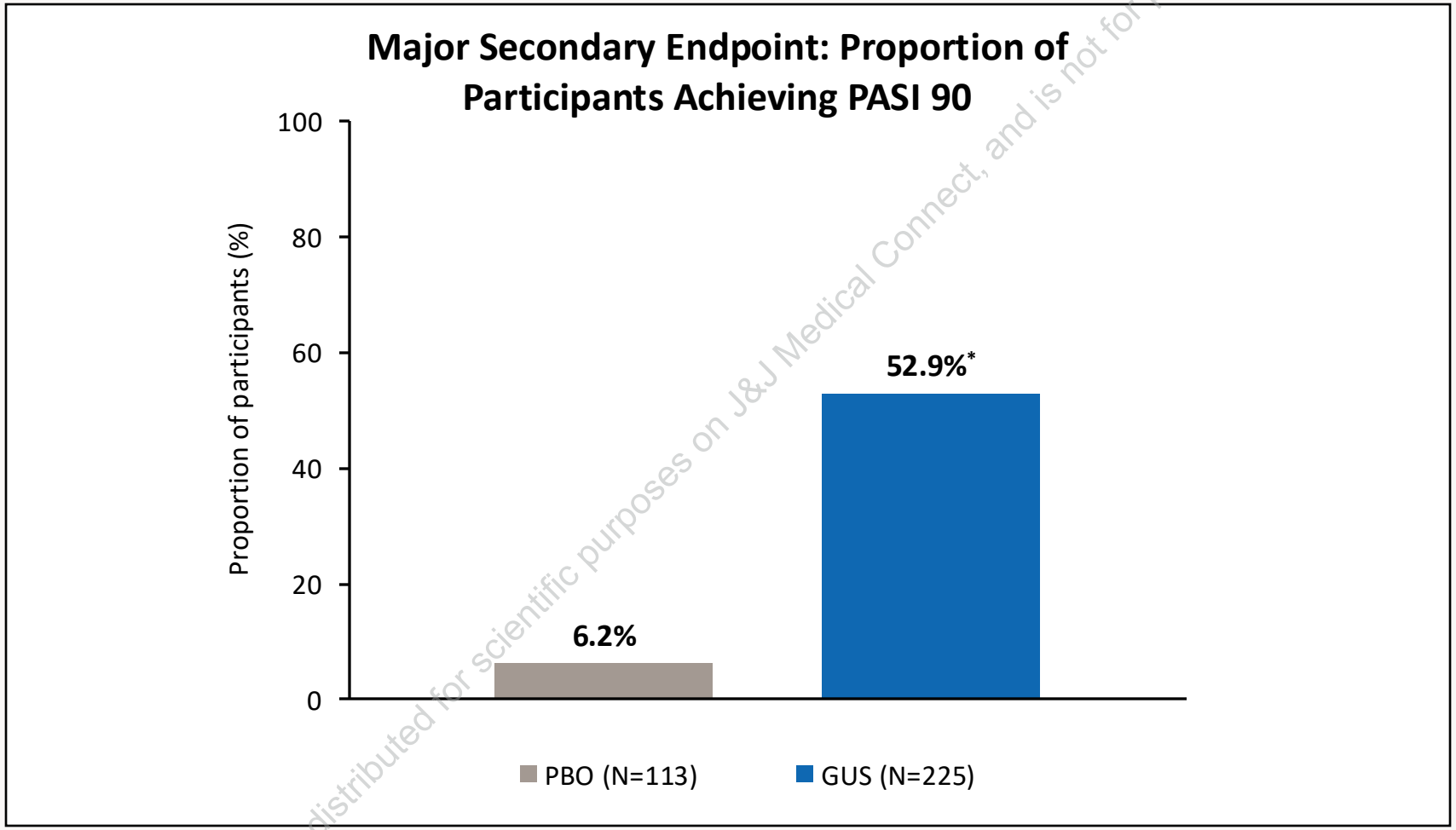
More than 70% of GUS-randomized participants achieved IGA 0/1 at Week 16, regardless of baseline BSA

- On average, 74.4% GUS-randomized participants achieved IGA 0/1



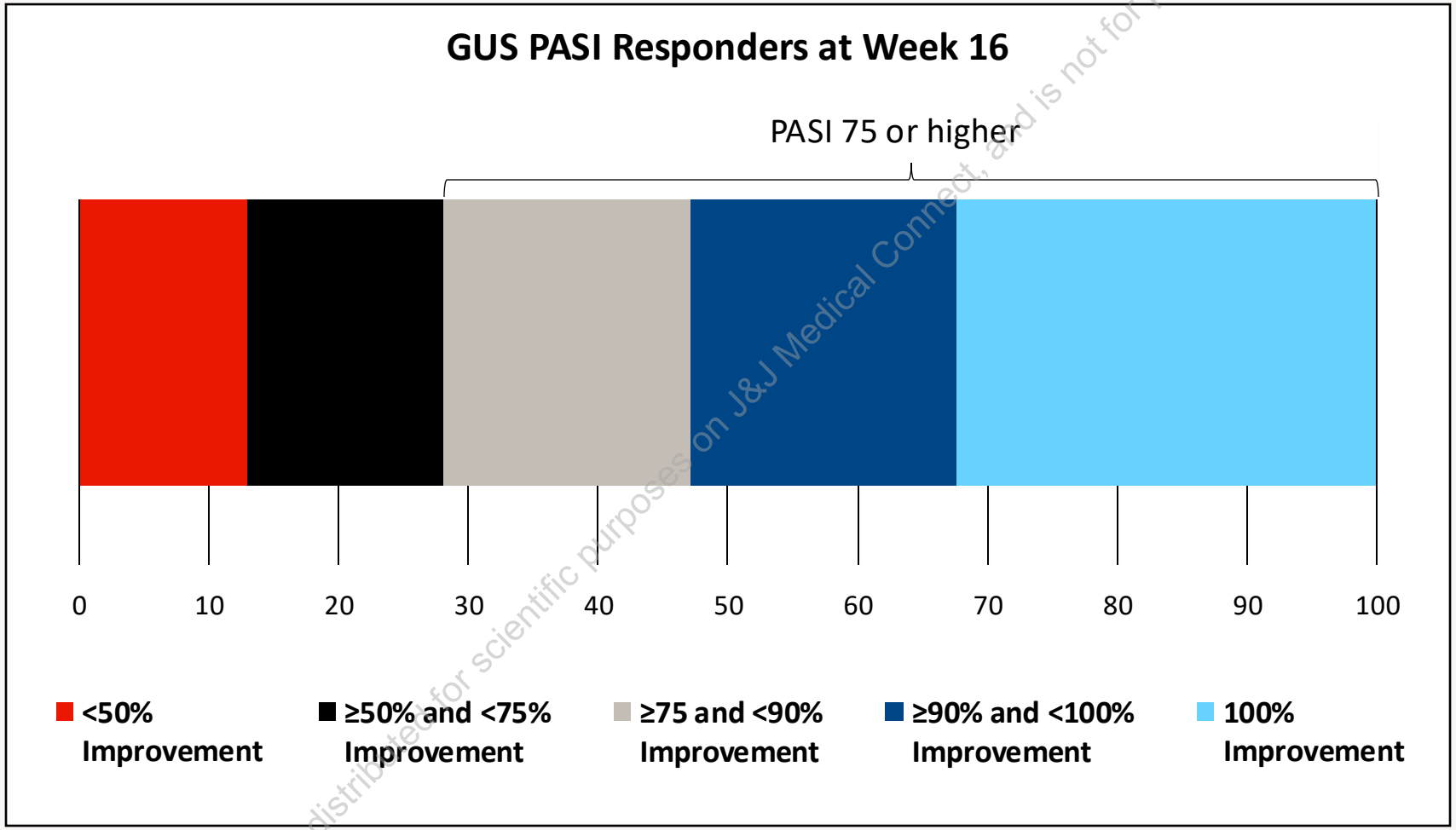
NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

A significantly greater proportion of GUS-randomized participants achieved PASI 90 compared to PBO-randomized participants at Week 16



*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.

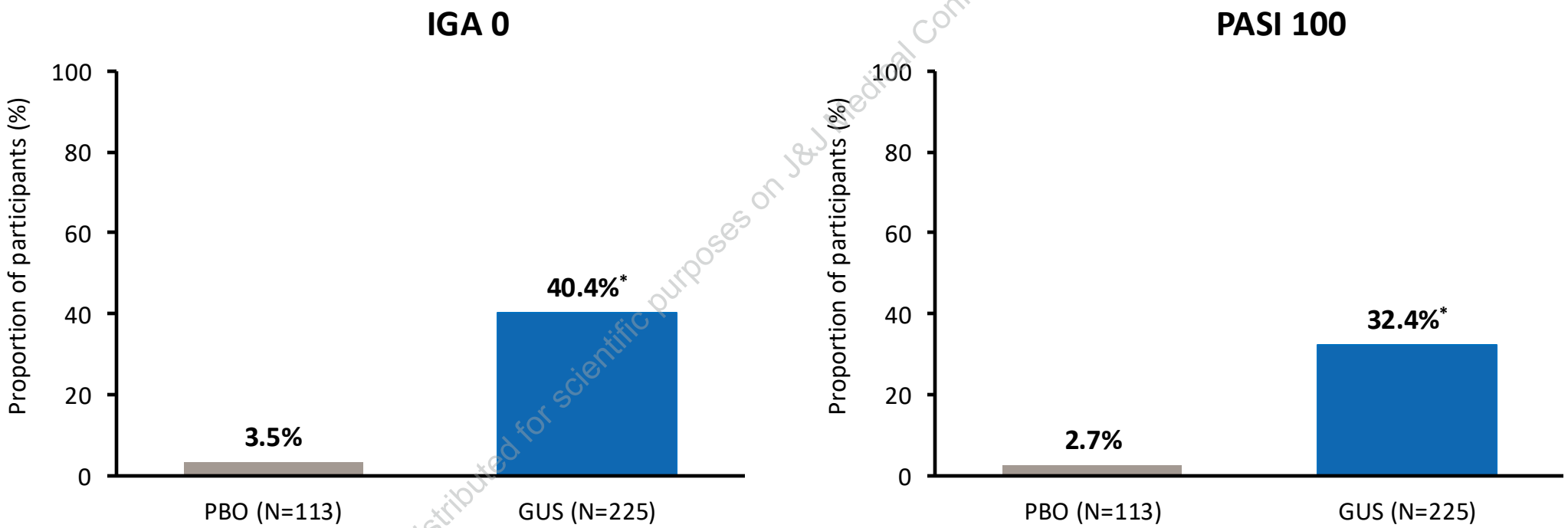
72.0% of GUS-randomized participants achieved a PASI 75 or higher response at Week 16



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.

Significantly greater proportions of GUS- vs PBO-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) at Week 16

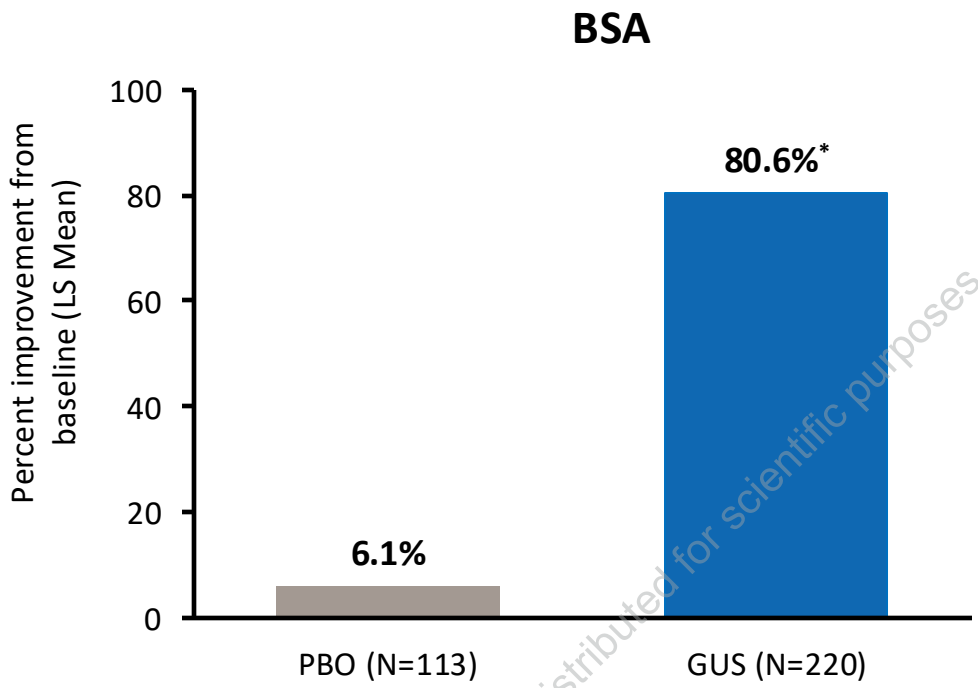
Major Secondary Endpoints: Proportions of Participants Achieving IGA 0 and PASI 100

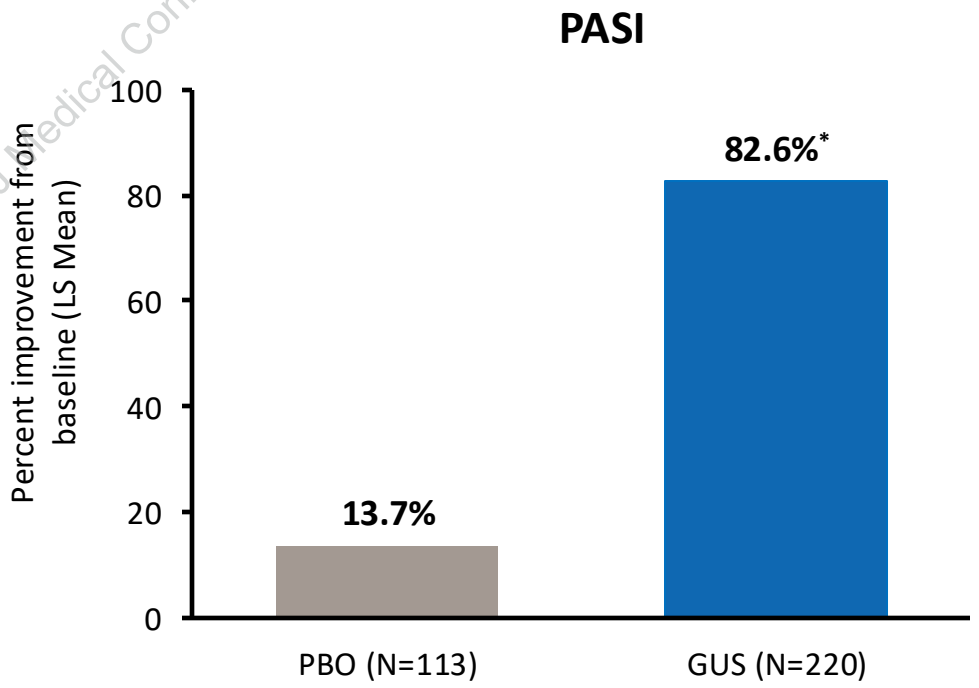


*p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital).
NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered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

Mean percent improvements in BSA and PASI were significantly greater for the GUS group compared to the PBO group at Week 16

Major Secondary Endpoints: Percent Improvements From Baseline (LS Mean) in BSA and PASI





*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.
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. **LS Mean**=least squares mean.

Safety outcomes were consistent with the established safety profile of GUS and no new safety signals were identified

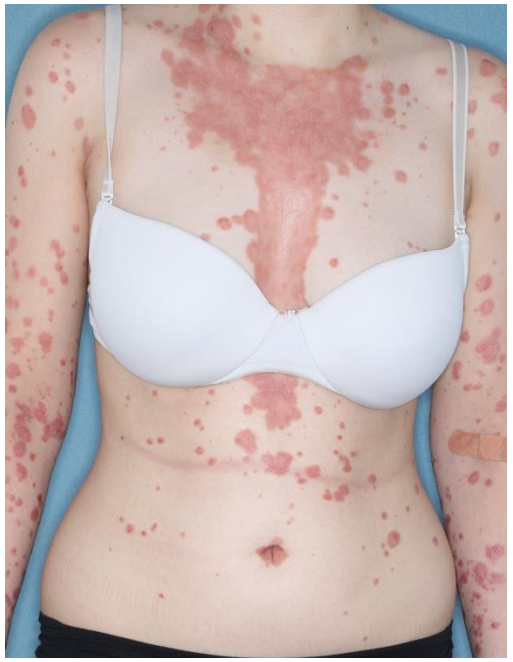
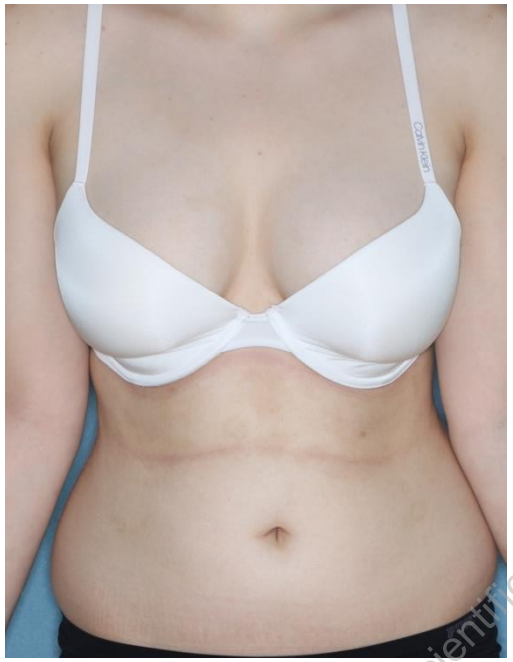
	PBO N=113	GUS N=225
Safety Outcomes Through Week 16		
Average duration of follow-up (weeks)	15.8	15.9
Participants with ≥1 AE	45 (39.8%)	85 (37.8%)
Participants with ≥1 AE leading to discontinuation of study agent	4 (3.5%)	0
Participants with ≥1 serious AE	1 (0.9%)	3 (1.3%)[a]
Participants with ≥1 injection site reaction	1 (0.9%)	6 (2.7%)[b]
Infections	23 (20.4%)	50 (22.2%)
Serious infections	1 (0.9%)	0
Major adverse cardiovascular event	0	1 (0.4%)[c]

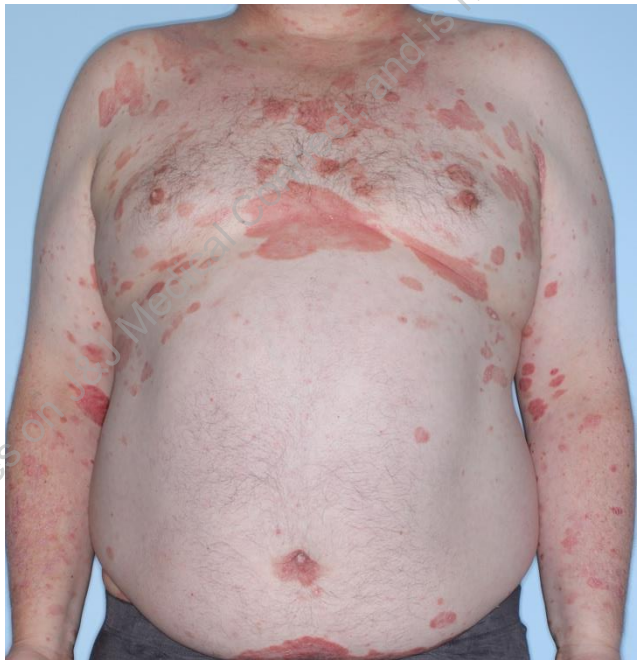
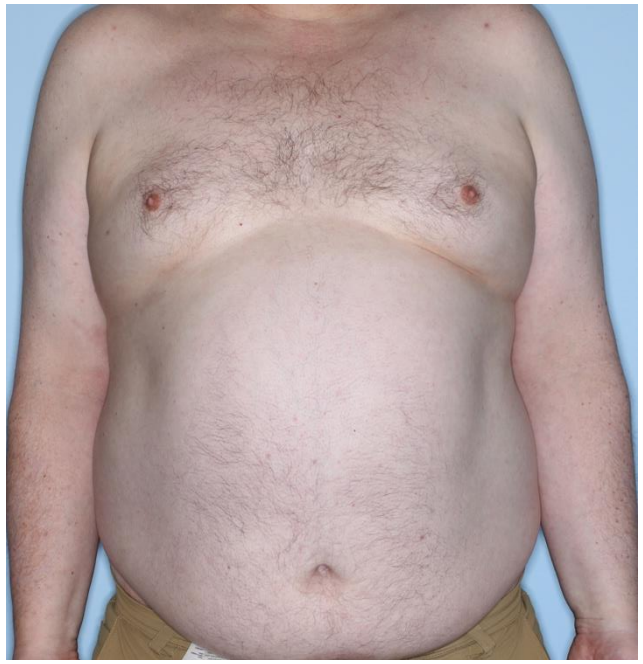
- **No cases of malignancy, active tuberculosis, inflammatory bowel disease, serum sickness/anaphylaxis, or death were reported**

Participants were counted only once for any given event, regardless of the number of times they experienced the event. AEs were coded using MedDRA Version 26.1.

[a]One event each of upper limb fracture, renal colic, and cerebrovascular accident; [b]Of the 6 injection site reactions, 4 were mild and 2 were moderate, none led to discontinuation; [c]The one major adverse cardiovascular event was a cerebrovascular accident within the first week of enrollment; the participant had a history of prior transient ischemic attack.

GUS-randomized participants who achieved IGA 0 and 100% improvement in BSA and PASI at Week 16

Week 0	Week 16
	
IGA: 3 BSA: 13.0% PASI: 12.4	IGA: 0 BSA: 0% PASI: 0
	BSA Improvement: 100% PASI Improvement: 100%

Week 0	Week 16
	
IGA: 3 BSA: 13.7% PASI: 9.0	IGA: 0 BSA: 0% PASI: 0%
	BSA Improvement: 100% PASI Improvement: 100%

Key Takeaways

- **Guselkumab is highly effective in participants with low BSA, moderate plaque psoriasis with high-impact site involvement; at Week 16:**
  - **More than 70% of guselkumab-randomized participants achieved the primary endpoint (IGA 0/1)**
  - **More than 30% of GUS-randomized participants achieved complete skin clearance (IGA 0 and PASI 100)**
  - **Mean percent improvements in BSA and PASI were >80% for the GUS group**
- **Consistent, significant improvements across multiple skin clearance measures, irrespective of baseline BSA, support the efficacy of guselkumab across a broad range of patients with PsO**
- **No new safety signals were identified**