VISIBLE: GUSELKUMAB IMPACT ON PSORIATIC ARTHRITIS AT WEEK 16 IN PARTICIPANTS WITH MODERATE-TO-SEVERE PSORIASIS ACROSS ALL SKIN TONES

Alice B. Gottlieb,[1] Amy McMichael,[2] Tina Bhutani,[3] Olivia Choi,[4] Theodore Alkousakis,[4] Jenny Jeyarajah,[5] Donna Febres,[4] Oyediran Adelakun,[4] Soumya D. Chakravarty,[4,6] Daphne Chan,[4] Joseph F. Merola[7]

[1]Icahn School of Medicine at Mt Sinai, New York, NY, USA; [2]Wake Forest School of Medicine, Winston-Salem, NC, USA; [3]Synergy Dermatology, San Francisco, CA, USA; [4]Johnson & Johnson, Horsham, PA, USA; [5]Johnson & Johnson, Spring House, PA, USA; [6]Drexel University College of Medicine, Philadelphia, PA, USA; [7]UT Southwestern Medical Center, Dallas, TX, USA

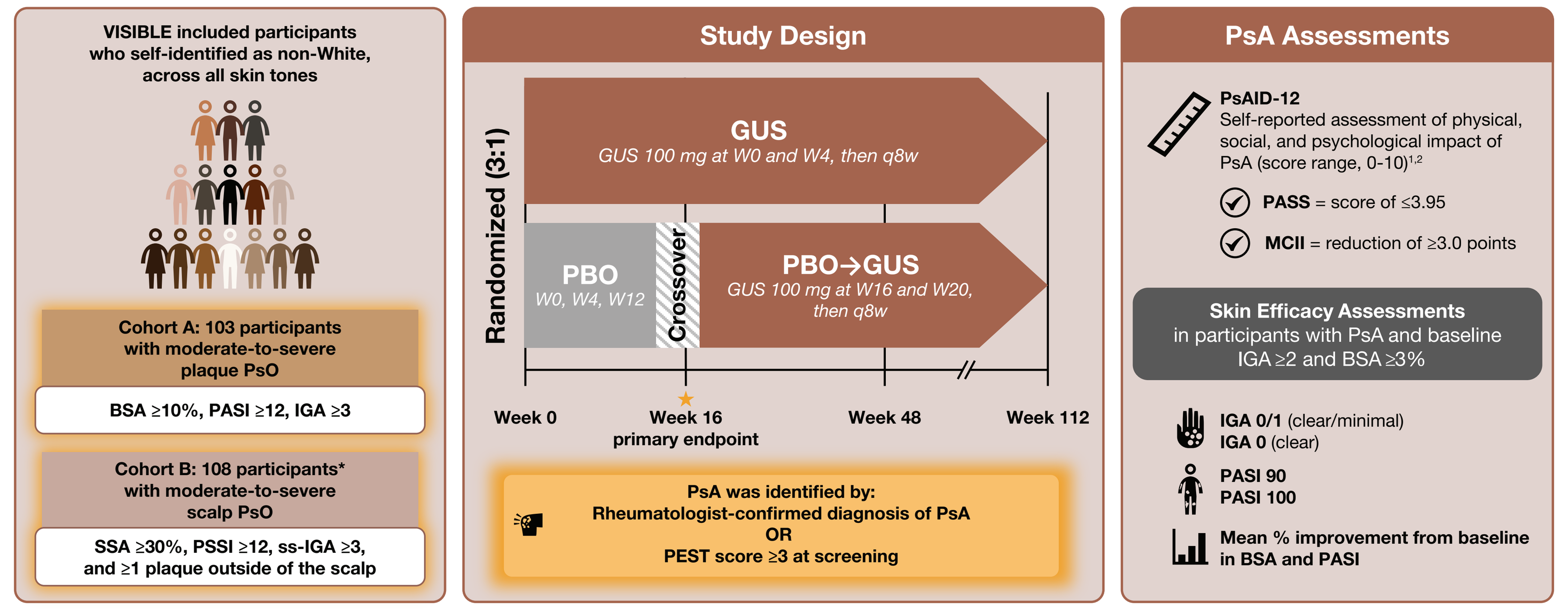
BACKGROUND

- **VISIBLE** is an ongoing Phase 3b study evaluating the efficacy and safety of **guselkumab** (GUS) in participants with moderate-to-severe plaque **psoriasis** (PsO) across all skin tones
- **Cohort A** enrolled participants with predominantly moderate-to-severe plaque PsO, and **Cohort B** enrolled participants with predominantly moderate-to-severe scalp PsO
- VISIBLE participants were evaluated for **psoriatic arthritis (PsA) at screening**; PsA was identified based on a rheumatologist-confirmed diagnosis of PsA or a Psoriasis Epidemiology Screening Tool (PEST) score ≥3

OBJECTIVE/METHODS

Objective

This Week 16 post hoc analysis evaluates efficacy and patient-reported outcomes with GUS treatment in VISIBLE Cohort A and Cohort B participants with PsA at baseline



*Cohort B efficacy analyses were performed for 102 participants who were correctly randomized. BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; MCII=Minimal clinically important improvement; PASI 90/PASI 100=≥90% or 100% improvement in Psoriasis Area and Severity Index; PASS=Patient Acceptable Symptom Score; PBO=Placebo; PEST=Psoriasis Epidemiology Screening Tool; PsA=Psoriatic arthritis; PsAID-12=Psoriatic Arthritis Impact of Disease-12; PSSI=Psoriasis Scalp Severity Index; q8w=Every 8 weeks; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

CONCLUSIONS

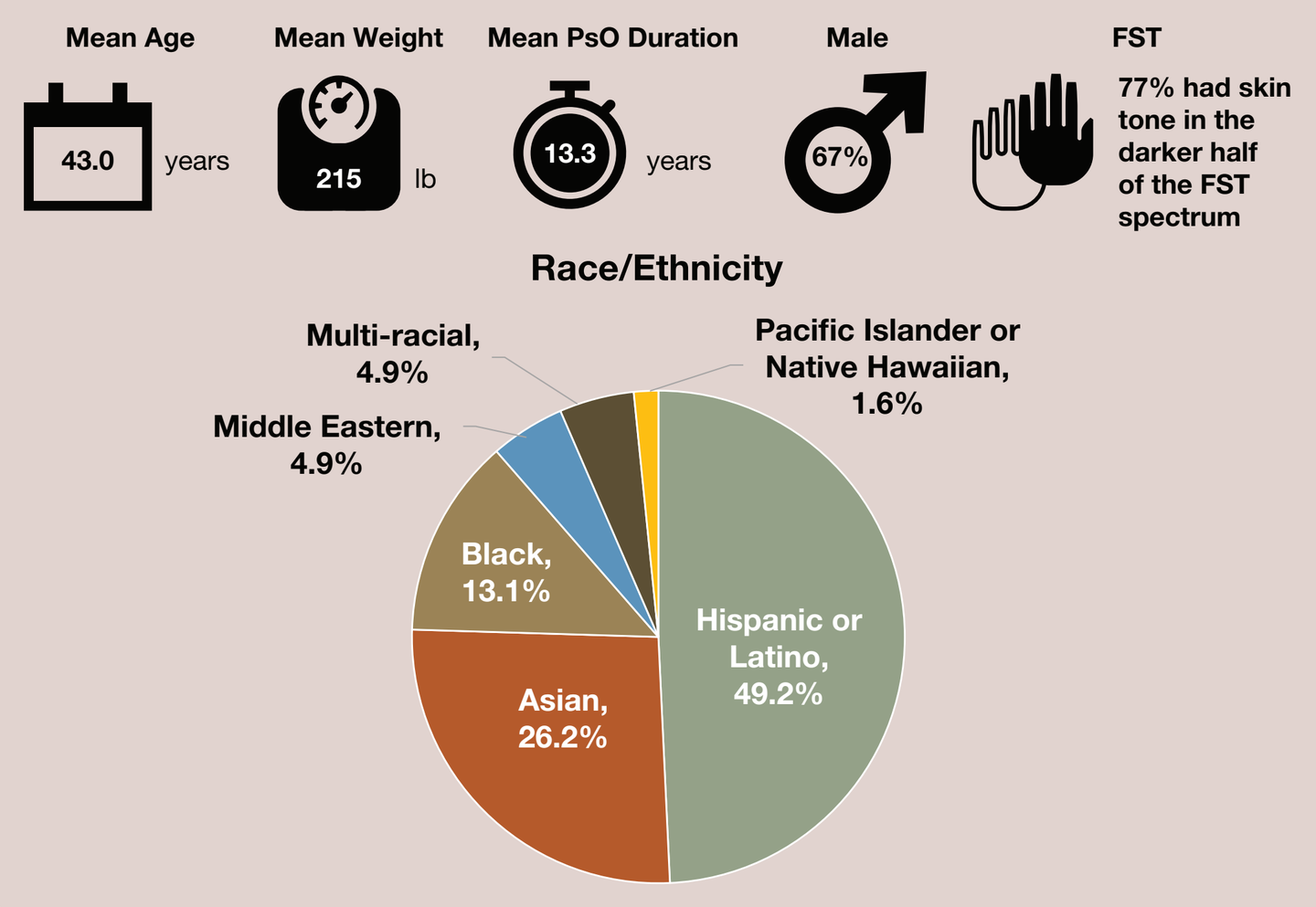
- **At baseline, the majority of VISIBLE study participants with PsA had PsAID-12 scores above the PASS threshold, indicating the need for improved PsA control across all skin tones**
- **After only 3 GUS doses, ~60% of these participants achieved clinically meaningful improvements in their PsA symptoms and health-related quality of life**
- **Consistent with the overall VISIBLE population, the majority of GUS-treated participants with PsA achieved significantly clearer skin as assessed by IGA, PASI, and BSA measures**

RESULTS

At baseline, 29.8% (61/205) of VISIBLE Cohort A and B participants had PsA

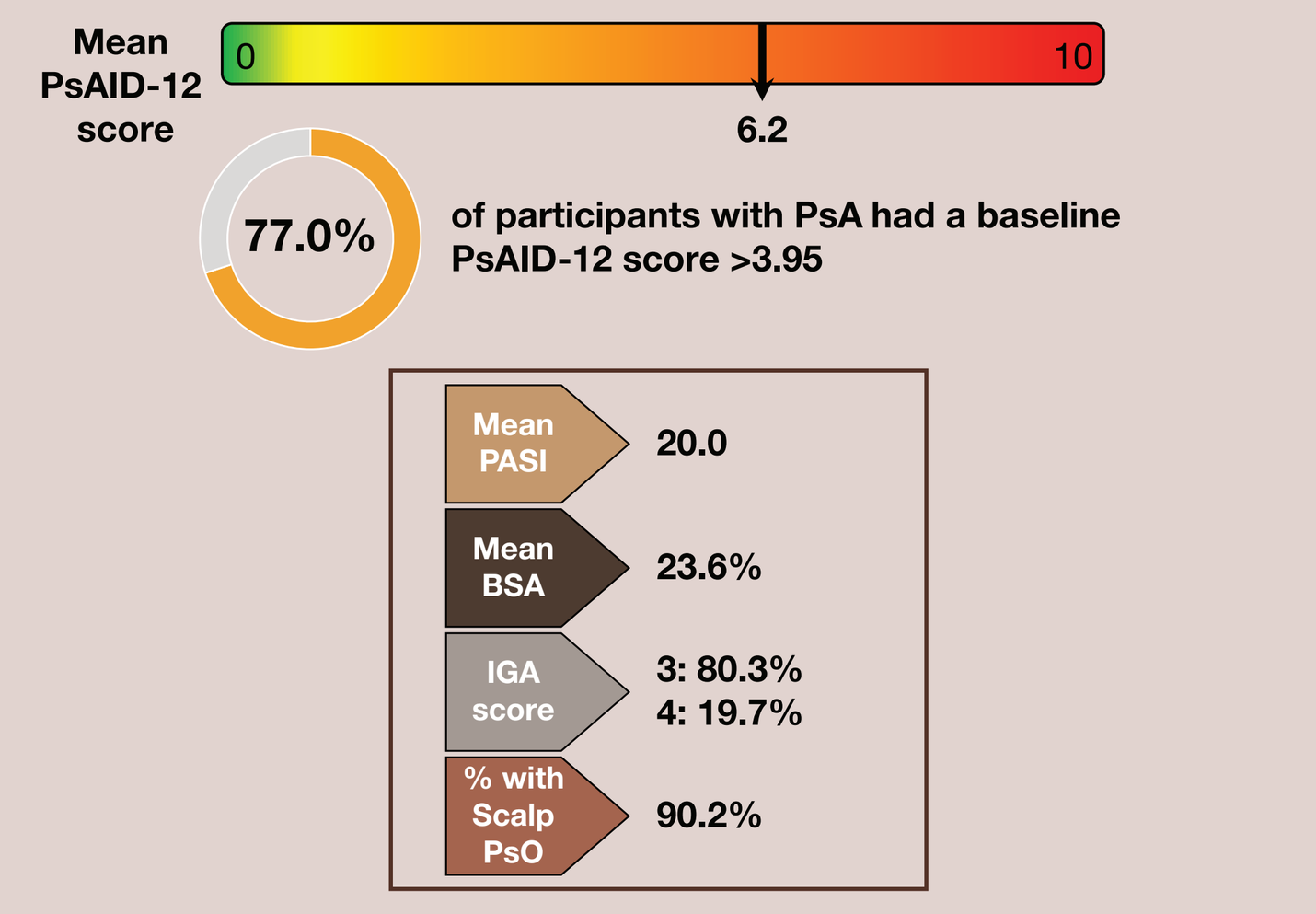
- Mean baseline data reflect moderate impact of PsA on health and extensive skin and scalp disease

Figure 1. Baseline Demographics



FST=Fitzpatrick Skin Type; PsO=Psoriasis; objective skin tone determined with colorimeter device measurement of non-sun exposed skin.

Figure 2. Baseline Disease Characteristics



BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsA=Psoriatic arthritis; PsAID-12=Psoriatic Arthritis Impact of Disease-12; PsO=Psoriasis.

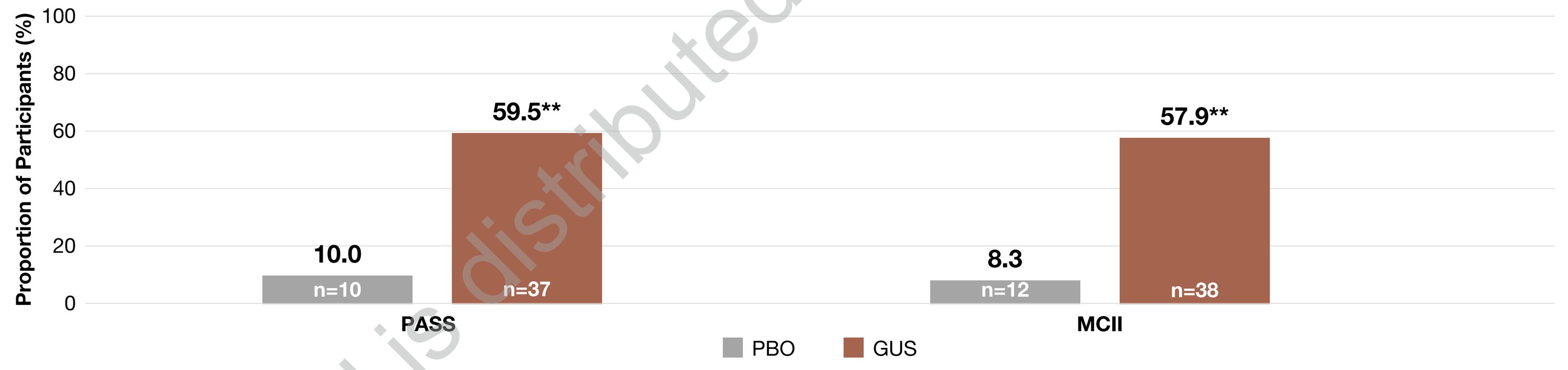
At Week 16, mean change from baseline in PsAID-12 was greater with GUS vs PBO, and mean improvement with GUS exceeded the MCII threshold of –3.0

Figure 3. Mean PsAID-12 Score at Baseline and Week 16

*nominal p<0.001 vs PBO. Δ=Least squares (LS) mean difference between baseline and Week 16 among participants with data at both timepoints. LS mean differences and p-values are based on an analysis of covariance model, with treatment group, baseline PsAID-12 score, and FST (I-III or IV-VI) as covariates; all p-values are nominal as this is a post hoc analysis. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening psoriasis, or initiated a prohibited psoriasis treatment prior to Week 16) were assigned a change from baseline=0. Missing data were not imputed. FST=Fitzpatrick Skin Type; GUS=Guselkumab; LS=Least squares; PBO=Placebo; PsAID-12=Psoriatic Arthritis Impact of Disease-12.

At Week 16, nearly 60% of GUS-treated participants with baseline PsAID-12 scores of >3.95 and ≥3.0, respectively, achieved PASS and MCII

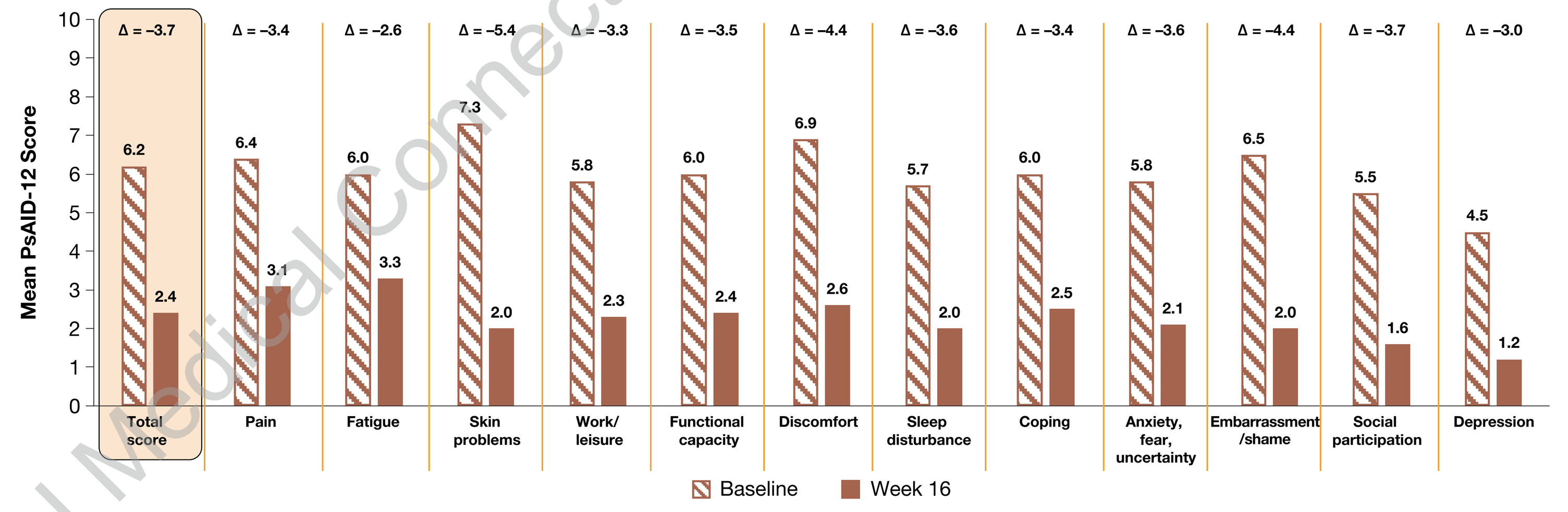
Figure 4. Achievement of PsAID-12 Response Thresholds at Week 16



**nominal p≤0.01 vs PBO. p-values are based on Fisher's exact test; all p-values are nominal as this is a post hoc analysis. Participants meeting treatment failure criteria or with missing data were considered nonresponders. Achievement of PASS (PsAID-12 ≤3.95) was assessed for participants with PsAID-12 scores >3.95 at baseline. Achievement of MCII (reduction of ≥3 points) was assessed for participants with PsAID-12 scores ≥3.0 at baseline. GUS=Guselkumab; PASS=Patient Acceptable Symptom Score; PBO=Placebo; MCII=Minimal clinically important improvement; PsAID-12=Psoriatic Arthritis Impact of Disease-12.

GUS treatment provided meaningful improvements across all PsAID-12 domains

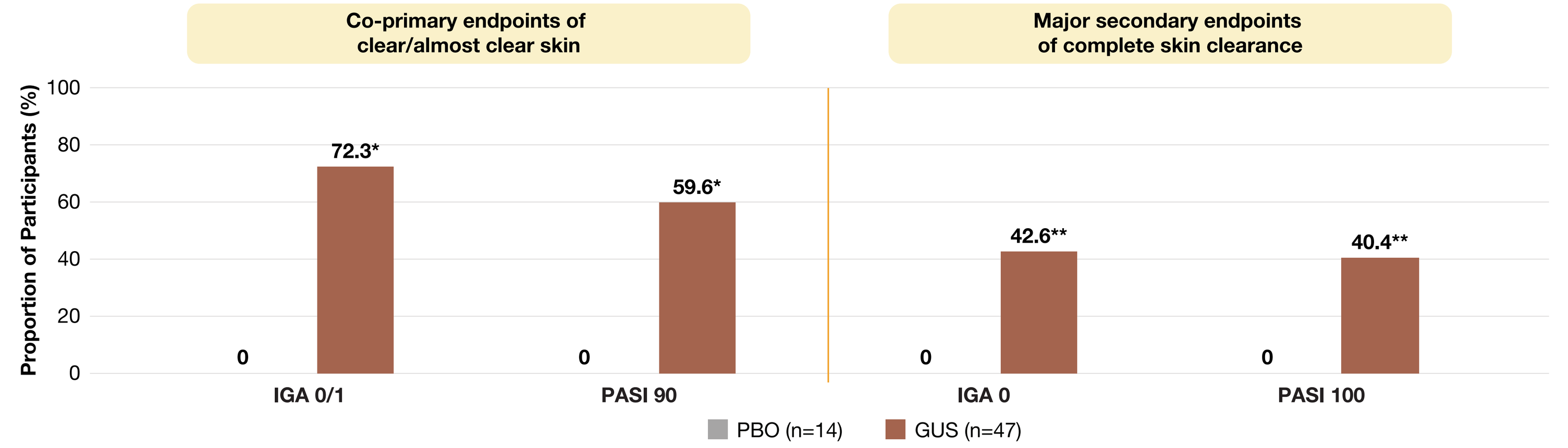
Figure 5. Improvements in PsAID-12 Component Scores From Baseline to Week 16 Among GUS-Treated Participants (n=40)



Δ=Mean change from baseline to Week 16; GUS=Guselkumab; PsAID-12=Psoriatic Arthrits Impact of Disease-12.

At Week 16, 72% and 60% of GUS-treated participants with PsA at screening achieved the co-primary endpoints of IGA 0/1 and PASI 90, respectively, and >40% had complete skin clearance vs 0 in the PBO group

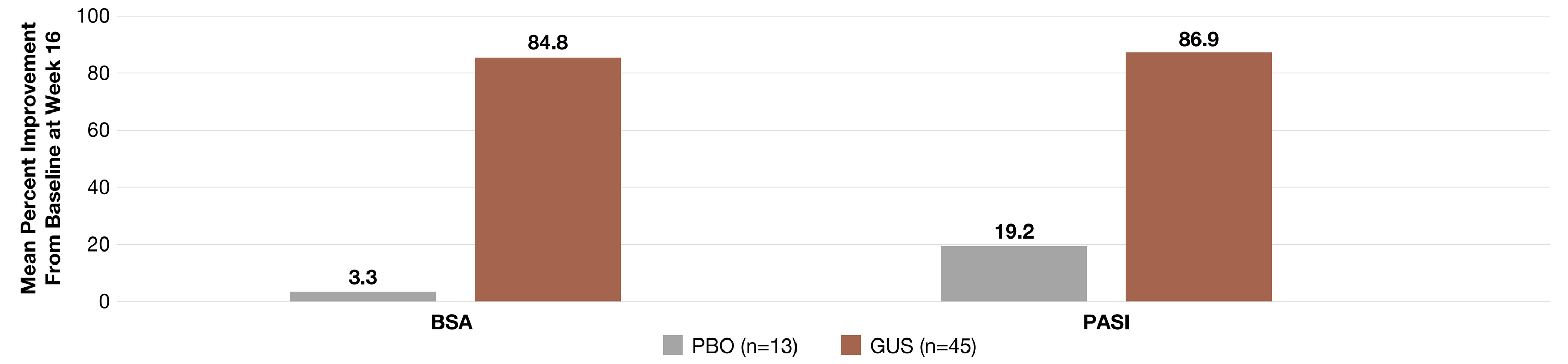
Figure 6. Achievement of Skin Efficacy Endpoints at Week 16 Among Participants With PsA at Screening and Baseline IGA ≥2 and BSA ≥3%



*nominal p<0.001 vs PBO. **nominal p<0.01 vs PBO. p-values are based on Fisher's exact test; all p-values are nominal as this is a post hoc analysis. Participants meeting treatment failure criteria or with missing data were considered nonresponders. BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsA=Psoriatic arthritis.

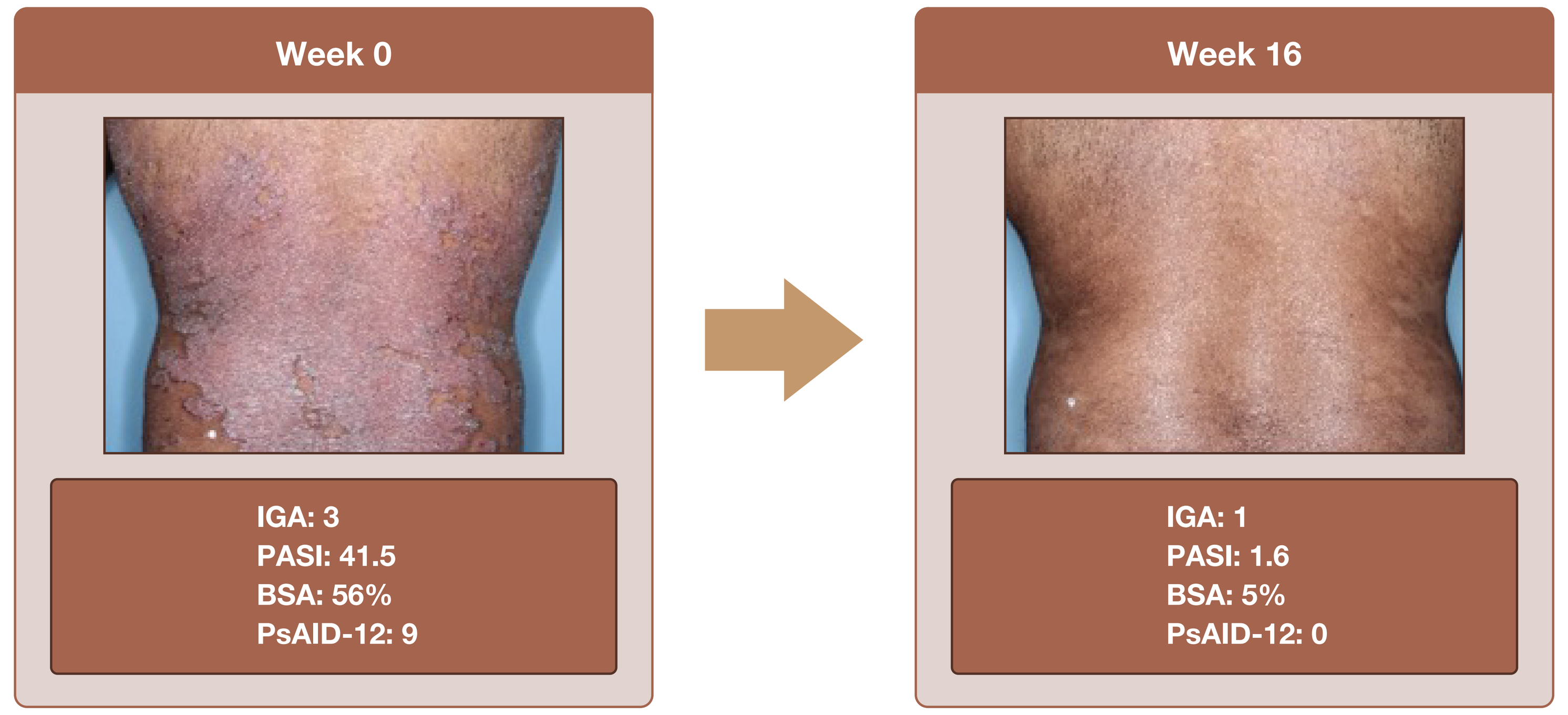
At Week 16, mean percent improvements from baseline in BSA and PASI were 84.8% and 86.9%, respectively, for GUS-treated participants with PsA at screening

Figure 7. Mean Percent Improvement in BSA and PASI From Baseline to Week 16



BSA=Body surface area; GUS=Guselkumab; PASI=Psoriasis Area and Severity Index; PBO=Placebo.

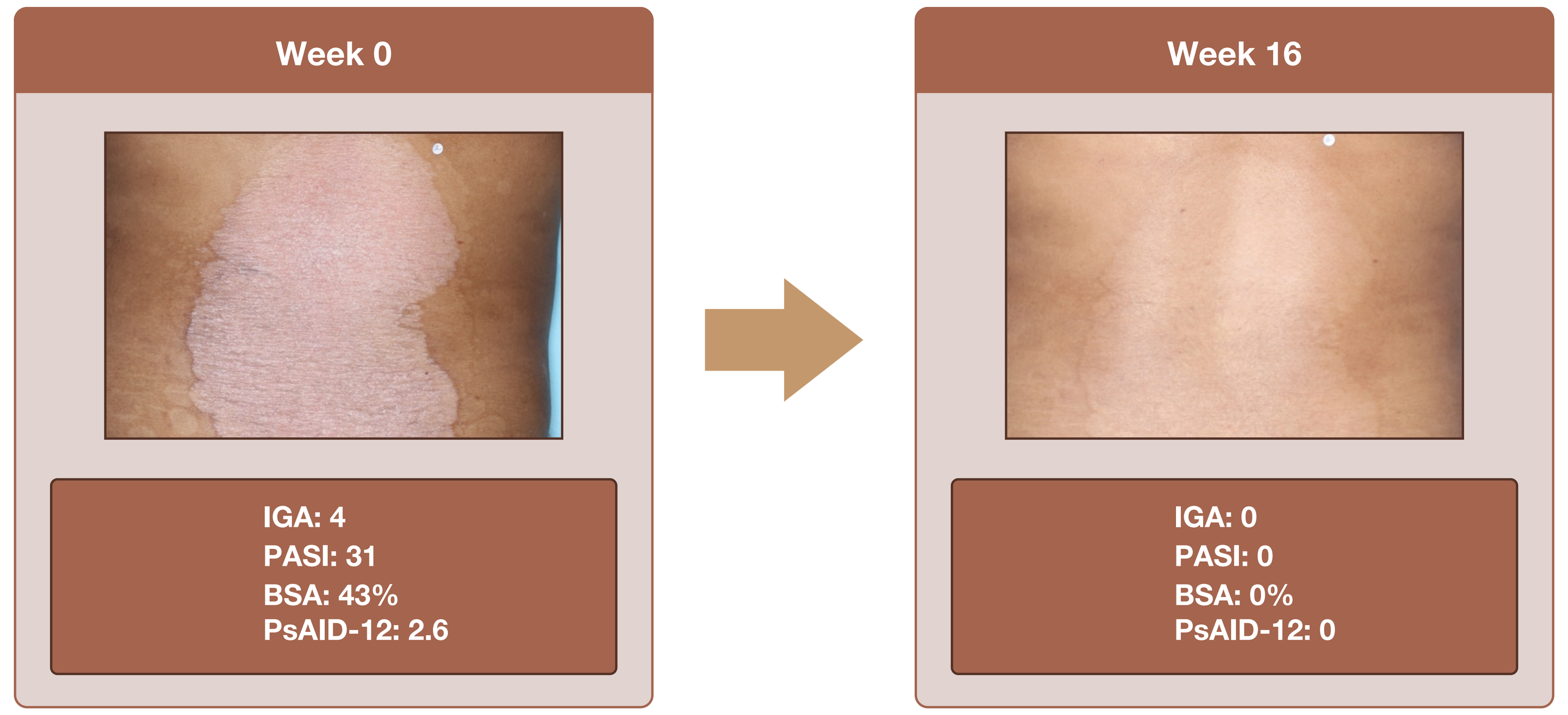
Figure 8. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16



PASI improvement: 96.1%
BSA improvement: 91.1%
PsAID-12 improvement: 100%

BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsAID-12=Psoriatic Arthritis Impact of Disease-12.

Figure 9. Participant Who Achieved IGA 0 and PASI 100 (Complete Clearance) at Week 16



PASI improvement: 100%
BSA improvement: 100%
PsAID-12 improvement 100%

BSA=Bosy surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsAID-12=Psoriatic Arthritis Impact of Diease-12.

References: 1. Gossec L, et al. *Ann Rheum Dis.* 2014;73:1012-9. 2. Holland R, et al. *J Psoriasis Psoriatic Arthritis.* 2022;5:12-22.

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