VISIBLE

Efficacy & Safety of Guselkumab vs Placebo in **Skin of Color (SOC)** Patients with Moderate to Severe Plaque or Scalp Psoriasis

VISIBLE: Guselkumab Impact On Psoriatic Arthritis Through Week 48 In Participants With Moderate-to-Severe Psoriasis Across All Skin Tones

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BACKGROUND

VISIBLE is a Phase 3b study that evaluated 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

Cohort B enrolled participants with predominantly moderate-to-severe scalp PsO

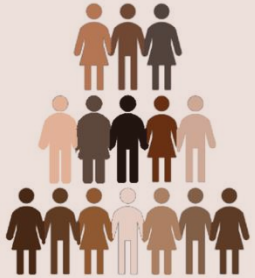
VISIBLE participants were evaluated for **psoriatic arthritis (PsA) at screening**

- PsA was identified based on a **rheumatologist-confirmed diagnosis** of PsA or a **Psoriasis Epidemiology Screening Tool (PEST) score ≥3**

OBJECTIVE/METHODS

This Week 48 post hoc analysis evaluates efficacy and patient-reported outcomes with GUS treatment in all VISIBLE participants with PsA at baseline (n=61; 29.8%)[a]

VISIBLE included participants who self-identified as non-white, across all objectively measured skin tones



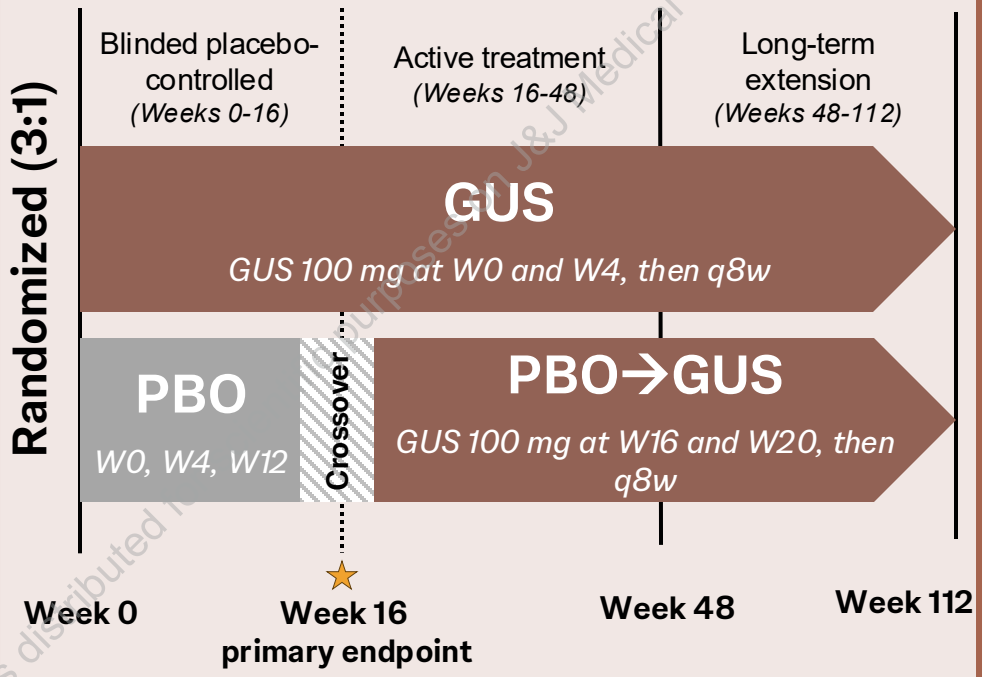
Cohort A: 103 participants with moderate-to-severe plaque PsO

BSA ≥10%, PASI ≥12, IGA ≥3

Cohort B: 108 participants[b] with moderate-to-severe scalp PsO

SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 plaque outside of the scalp

Study Design



PsA Assessments

PsAID-12 was assessed for participants identified as having PsA at screening (rheumatologist-confirmed diagnosis of PsA or PEST≥3)

PsAID-12 is a self-reported assessment of physical, social, and psychological impact of PsA (score range, 0-10)[1,2]

- **PASS** = score of ≤3.95
- **MCII** = reduction of ≥3.0 points

Skin Efficacy Assessments in participants with PsA and baseline IGA ≥2 and BSA ≥3%

- **IGA 0/1** (clear/minimal)
  IGA 0 (clear)
- **PASI 90**
  PASI 100
- **Mean % improvement in BSA and PASI**

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[a]Efficacy Analysis Set: VISIBLE Cohorts A and B, 29.8% (n=61) had PsA, IGA ≥2, and PASI ≥3 at baseline. [b]Cohort B efficacy analyses were performed for 102 participants who were correctly randomized. BSA=Body surface area; 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; PsAID-12=Psoriatic Arthritis Impact of Disease-12; PSSI=Psoriasis Scalp Severity Index; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

RESULTS

At baseline, 29.8% (61/205) of VISIBLE participants had PsA

- Mean baseline disease characteristics reflect moderate symptoms and impacts of PsA based on PsAID-12 scores, and extensive skin and scalp disease

Figure 1. Baseline Demographics

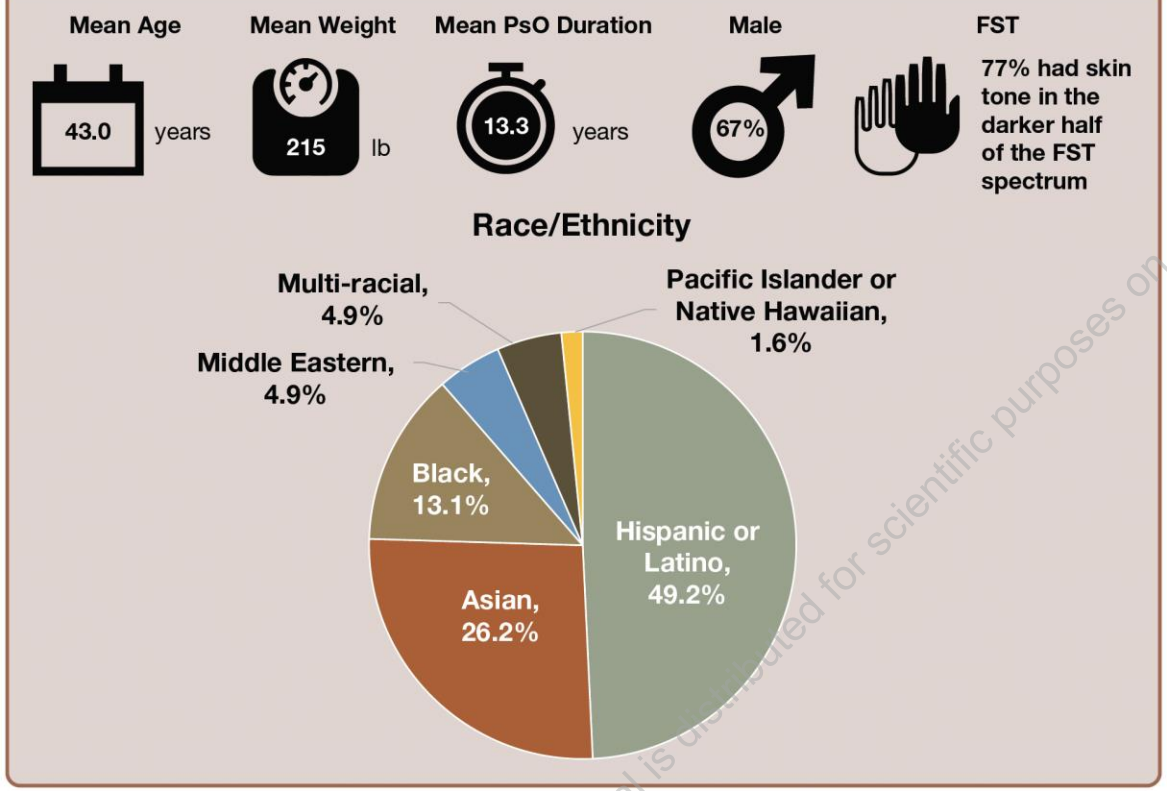
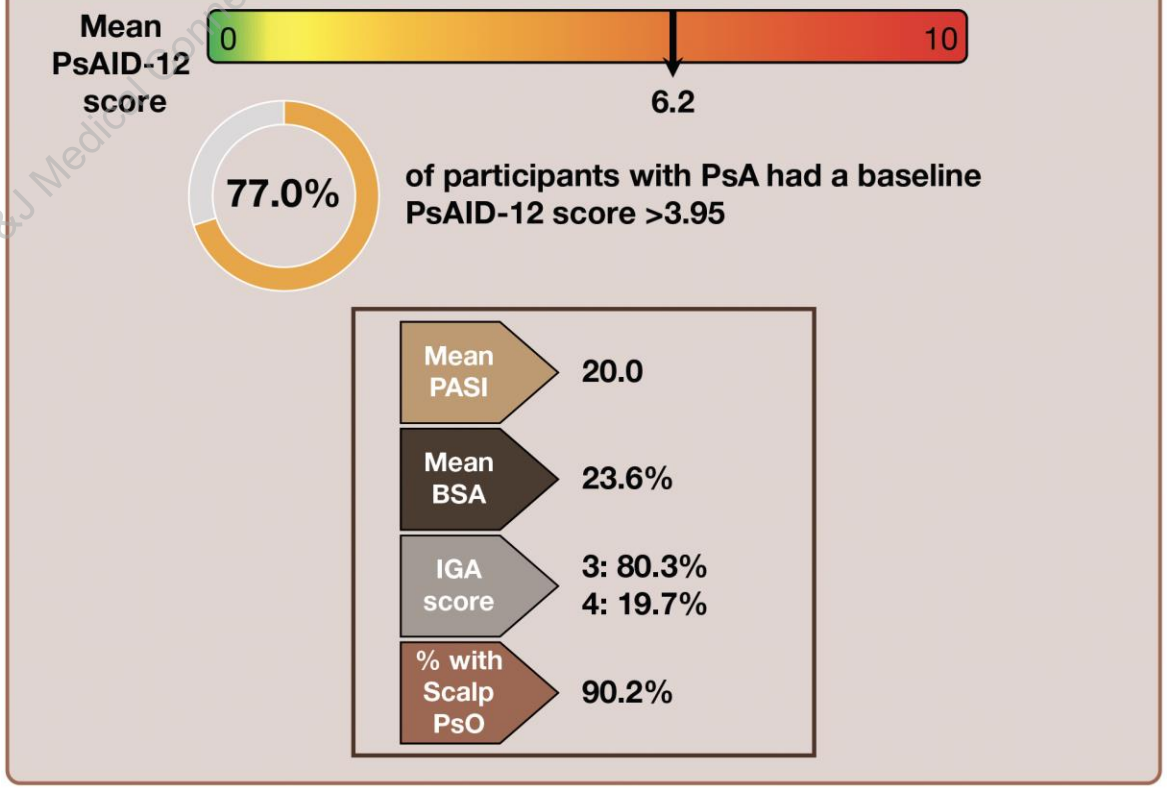


Figure 2. Baseline Disease Characteristics

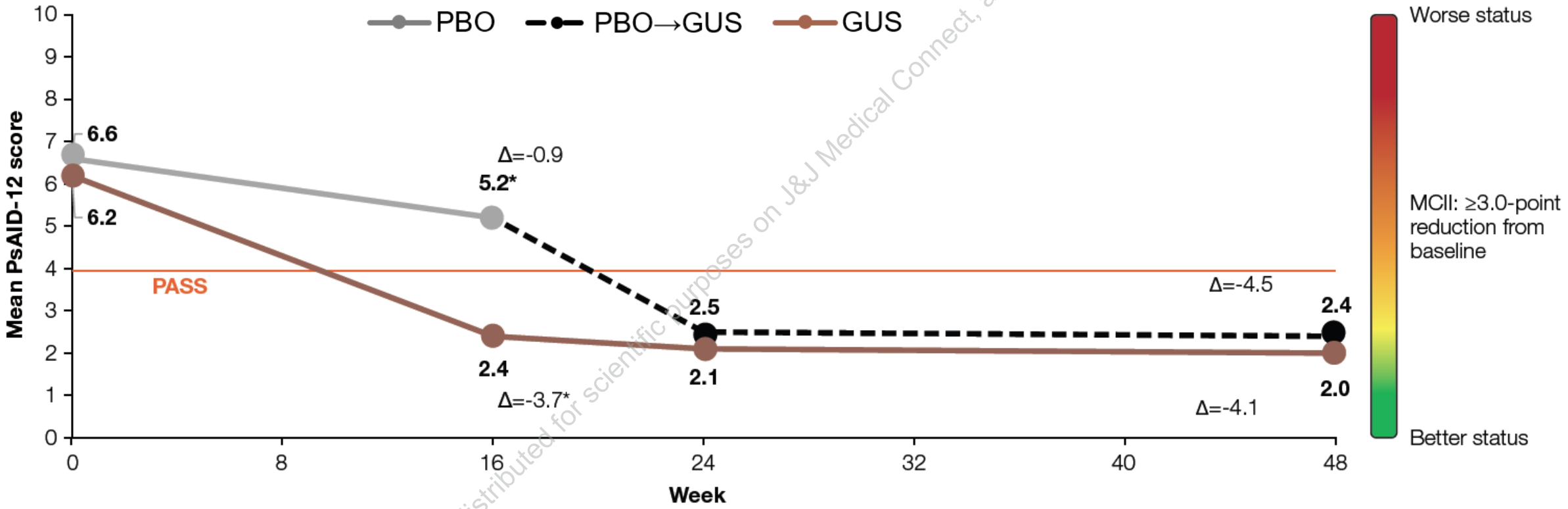


FST=Fitzpatrick Skin Type; objective skin tone determined with colorimeter device measurement of non-sun exposed skin.

RESULTS

At Week 16, mean change from baseline in PsAID-12 was greater with GUS vs PBO, and mean PsAID-12 improvement with GUS exceeded the MCII threshold of –3.0, which further improved through Week 48

Figure 3. Mean PsAID-12 through Week 48[a]

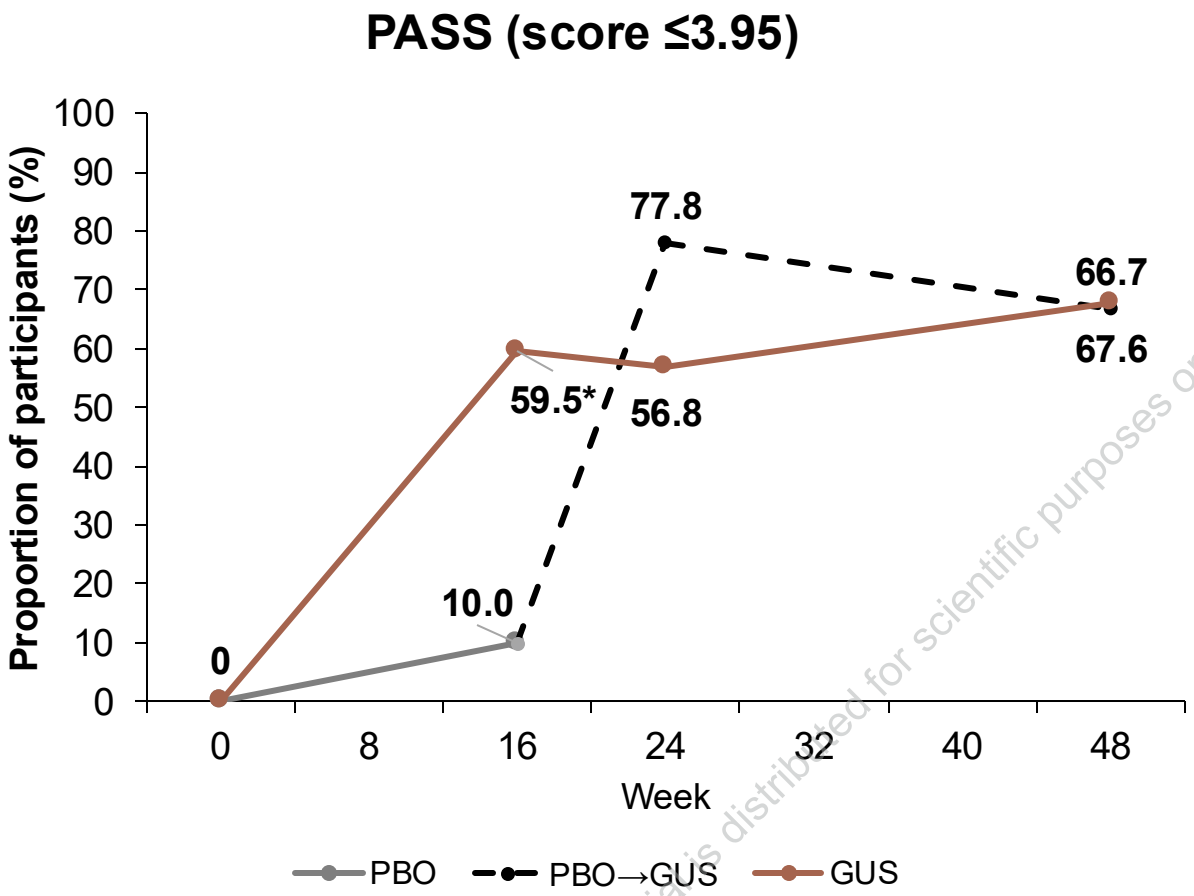


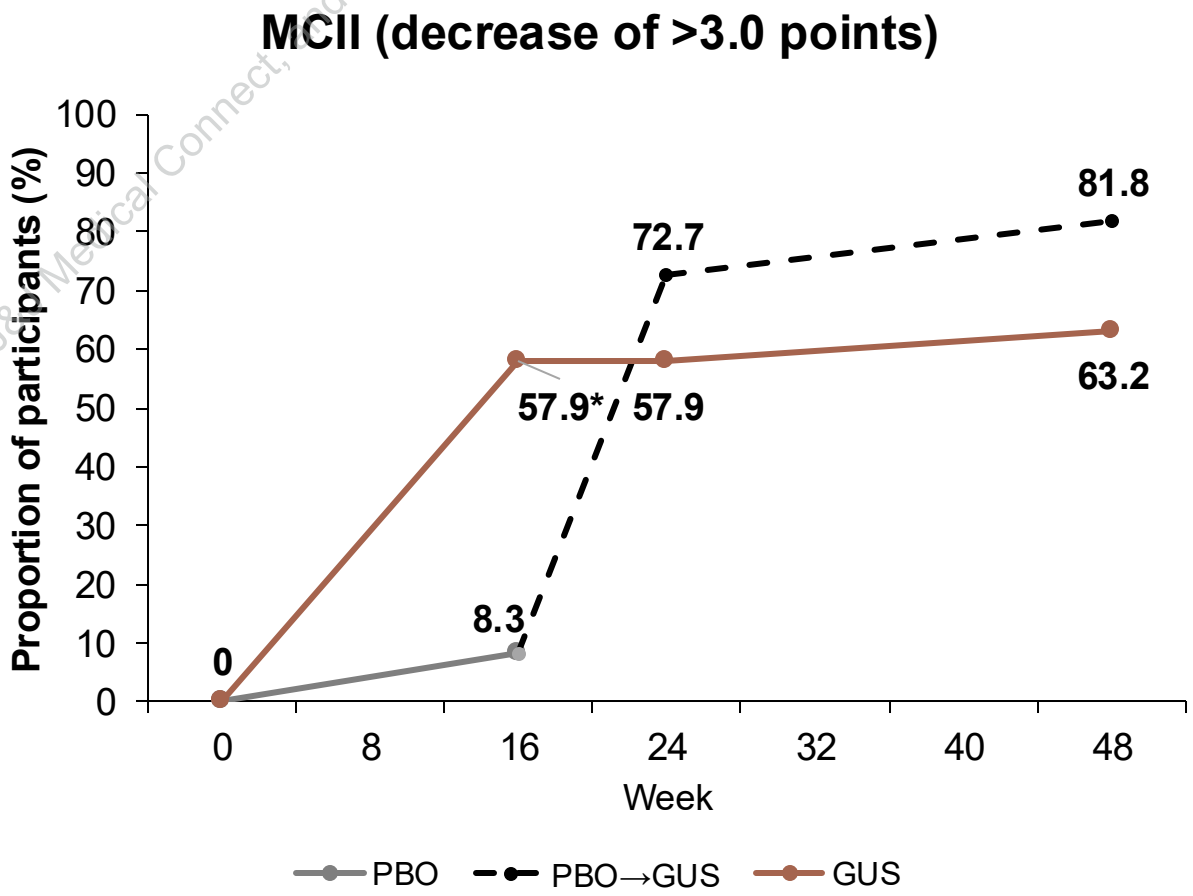
[a]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.001 vs PBO. Δ=Least squares (LS) mean difference between baseline and Week 16 or 48 among participants with data at both timepoints. Δ and p-values are based on an analysis of covariance model, with treatment group, baseline PsAID-12 score, and FST (I-III or IV-VI) as covariates. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening PsO, or initiated a prohibited PsO treatment prior to Week 16) were assigned a change from baseline=0. Missing data were not imputed. MCII=Minimal clinically important improvement (reduction of ≥3.0 points).

RESULTS

At Week 48, more than 60% of GUS-treated participants with PsA and baseline PsAID-12 scores of >3.95 and ≥3.0, respectively, achieved PASS and MCII

Figure 4. Achievement of PsAID-12 Response Thresholds Through Week 48[a]





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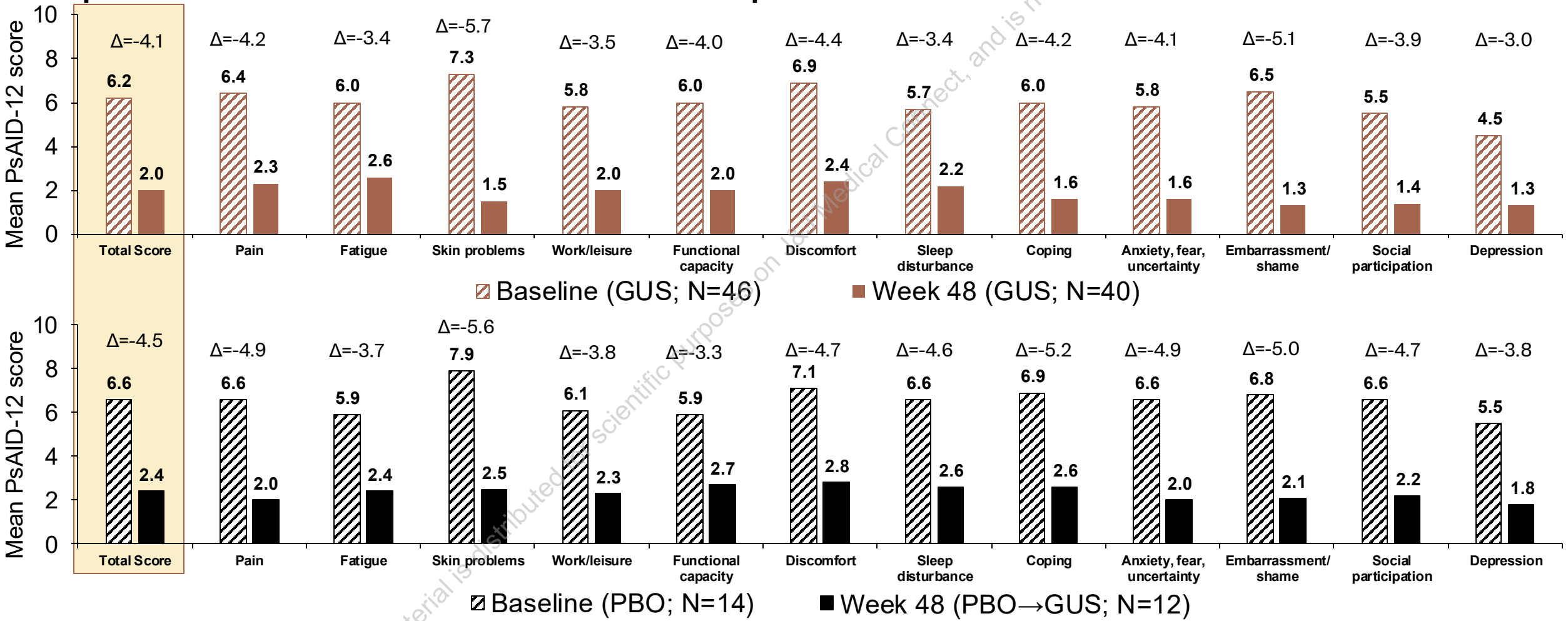
[a]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.05 GUS vs PBO. LS mean differences and p-values are based on an analysis of covariance model, with treatment group, baseline PsAID-12 score, and FST (I-III or IV-VI) as covariates. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening PsO, or initiated a prohibited PsO treatment prior to Week 16) were assigned a change from baseline=0. Missing data were not imputed. MCII=Minimal clinically important improvement (reduction of ≥3.0 points); PASS=Patient Acceptable Symptom Score (score of ≤3.95).

RESULTS

GUS treatment provided meaningful improvements across all PsAID-12 domains

Figure 5. Improvements in PsAID-12 Component Scores From Baseline to Week 48 Among GUS-Treated Participants and Week 16 PBO→GUS Crossover Participants[a]

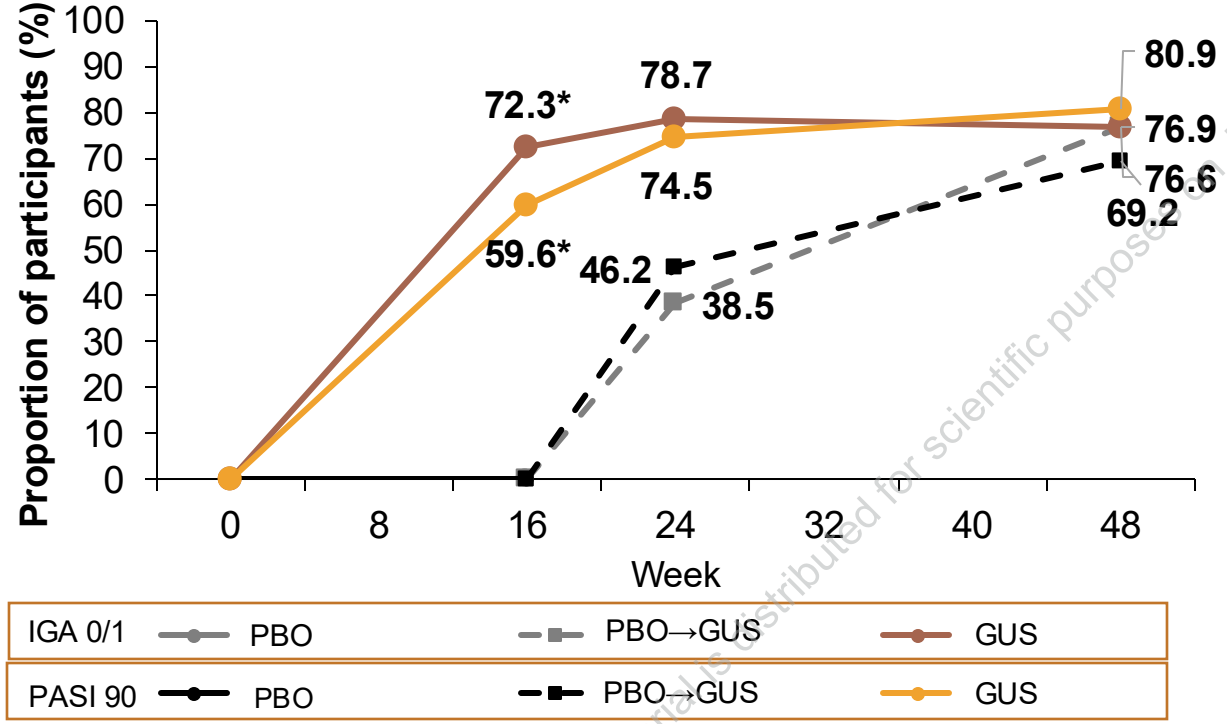


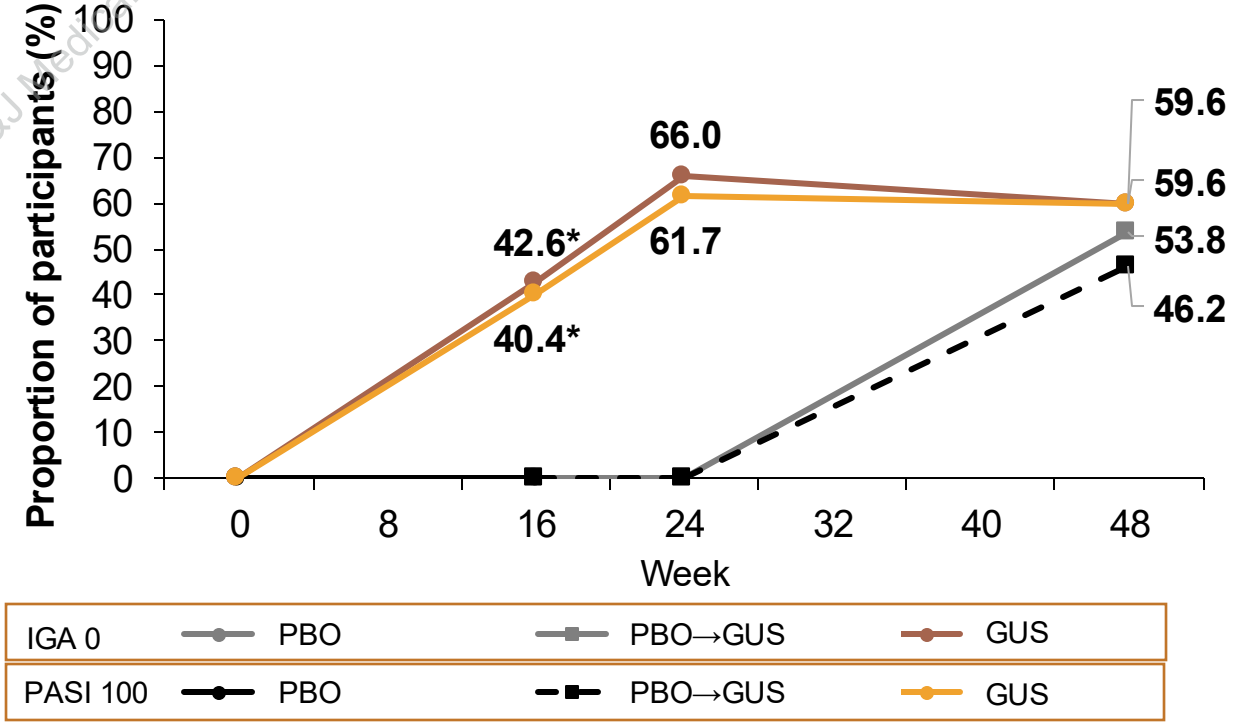
[a]Efficacy Analysis Set: participants with PsA at baseline. Δ=Mean change from baseline to Week 48. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening PsO, or initiated a prohibited PsO treatment prior to Week 16) were assigned a change from baseline=0. 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 Week 48 analysis.

RESULTS

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

Figure 6. Achievement of Skin Efficacy Endpoints Through Week 48 Among Participants With PsA at Screening and Baseline IGA ≥2 and BSA ≥3%[a]



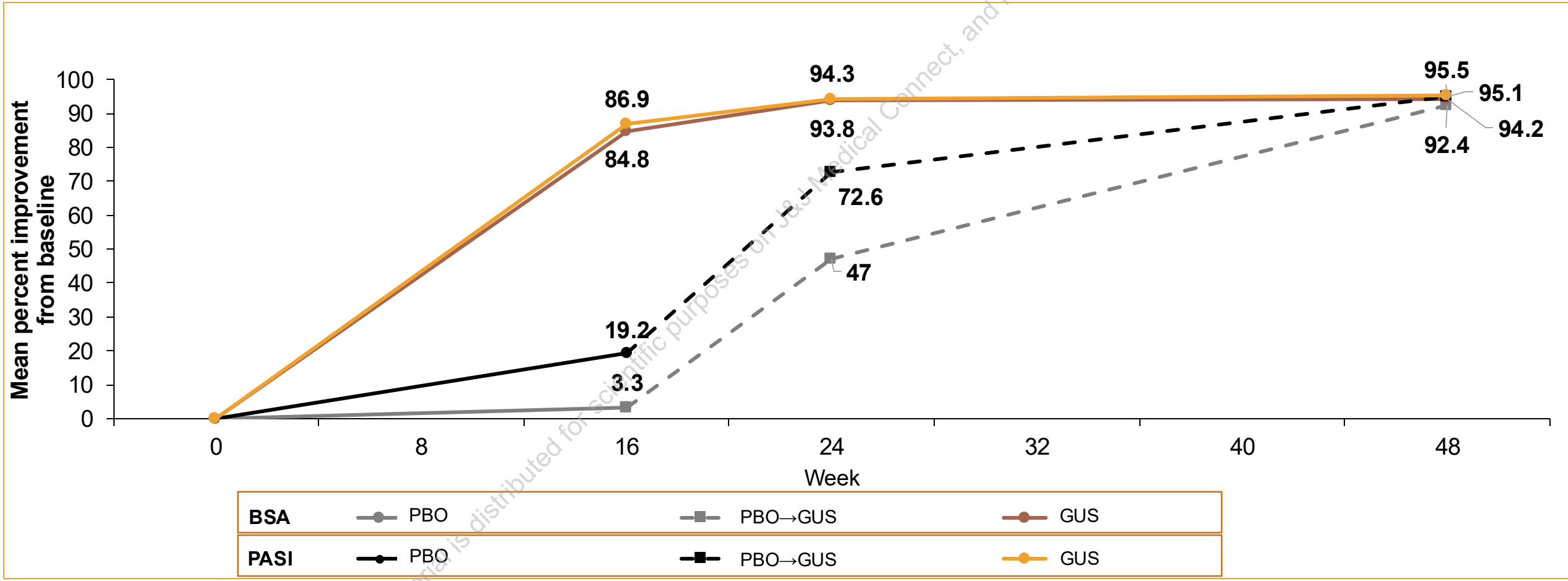


[a]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.05 GUS vs placebo. p-values are based on Fisher's exact test. Participants meeting treatment failure criteria or with missing data were considered nonresponders.

RESULTS

At Week 48, mean percent improvements from baseline in BSA and PASI were above 92% for GUS-treated participants with PsA at screening[a]

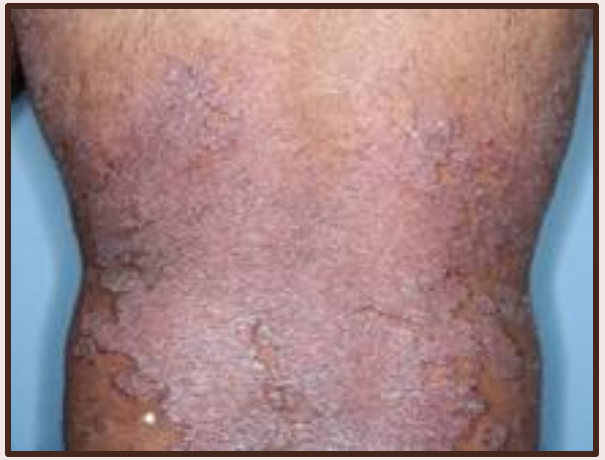
Figure 7. Mean Percent Improvement in BSA and PASI From Baseline through Week 48



[a]Efficacy Analysis Set: participants with PsA at baseline. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening PsO, or initiated a prohibited PsO treatment prior to Week 16) were assigned a change from baseline=0. For participants who were randomized to placebo at Week 0, only those participants who crossed over to GUS at or after Week 16 were included.

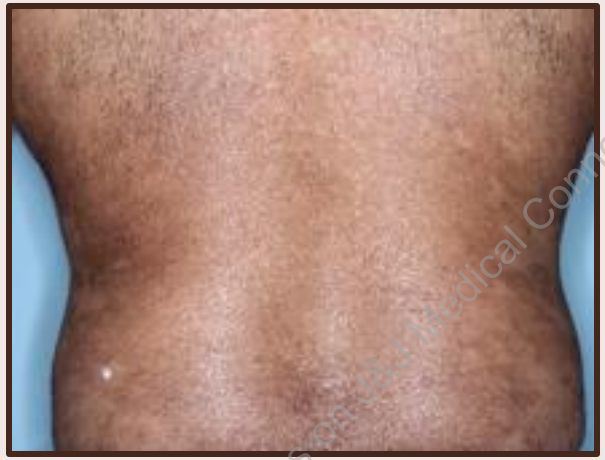
Figure 8. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16

Week 0



IGA: 3
PASI: 41.5
BSA: 56%
PsAID-12: 9

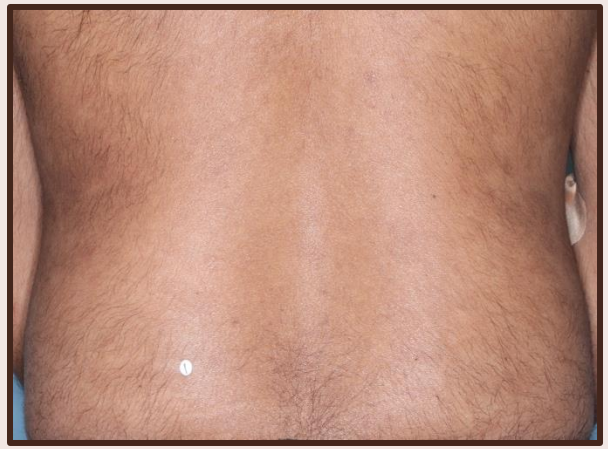
Week 16



IGA: 1
PASI: 1.6
BSA: 5%
PsAID-12: 0

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

Week 48



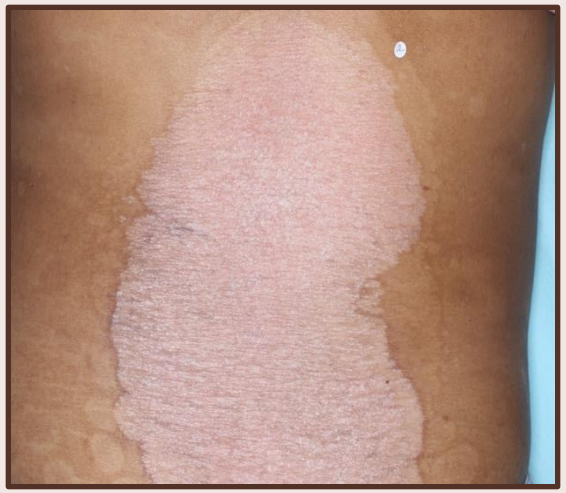
IGA: 0
PASI: 0
BSA: 0
PsAID-12: 0

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

RESULTS

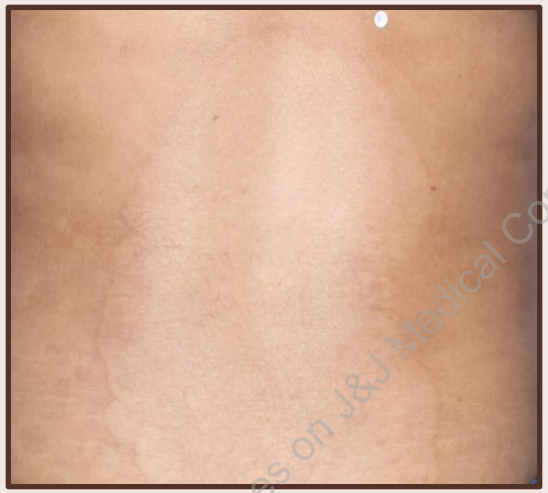
Figure 9. Participant Who Achieved IGA 0 and PASI 100 (Complete Clearance) at Week 16

Week 0



IGA: 4
PASI: 31
BSA: 43%
PsAID-12: 2.6

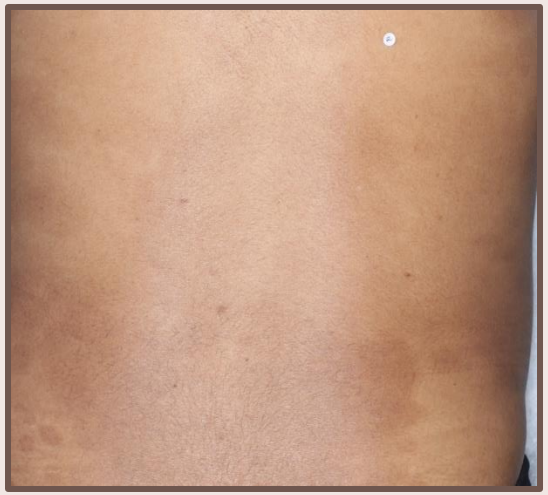
Week 16



IGA: 0
PASI: 0
BSA: 0%
PsAID-12: 0

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

Week 48



IGA: 0
PASI: 0
BSA: 0%
PsAID-12: 0

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

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

After only 3 GUS doses, ~60% of these participants achieved clinically meaningful improvements in their PsA symptoms and health-related quality of life; these improvements continued and were maintained through Week 48

Consistent with the overall VISIBLE population, the majority of GUS-treated participants with PsA achieved notably clearer skin as assessed by IGA, PASI, and BSA measures

References

1. Gossec, L, et al. *Ann Rheum Dis*. 2014;73:1012-9.

2. Holland R, et al. *J Psoriasis Psoriatic Arthritis*. 2020;5:12-22.

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