



SHADOWS OF INFLAMMATION: EXPLORING POST-INFLAMMATORY PIGMENT CHANGES IN PSORIASIS IN VISIBLE, A PHASE 3B RANDOMIZED CONTROLLED STUDY OF GUSELKUMAB FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS DEDICATED TO PEOPLE OF COLOR

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BACKGROUND

VISIBLE is an ongoing, **first-of-its-kind**, large-scale, phase 3b, randomized, double-blind, placebo (PBO)-controlled study to evaluate efficacy and safety of **guselkumab** (GUS) for moderate-to-severe **plaque psoriasis** (PsO) across all skin tones. **VISIBLE** was uniquely prospectively designed to collect data on **post-inflammatory pigment alteration** (PIPA)

PIPA secondary to PsO more frequently impacts individuals with **skin of color**^{1,2}

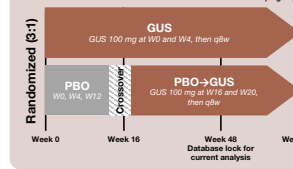
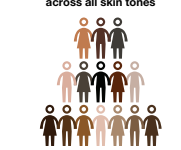
In one survey of biologic-treated PsO patients, over **80%** considered **PIPA** to be an important but **neglected problem**³

OBJECTIVE/METHODS

Objective
Evaluate impact of PIPA on quality-of-life (QoL) using the patient-reported Skin Discoloration Impact Evaluation Questionnaire (SDIEQ)⁴ in conjunction with the Dermatology Life Quality Index (DLQI)⁵ and PROMIS-29 depression measures

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

VISIBLE Study Design



Cohorts A and B Analysis Population (N=205)

Outcomes
• Pigmentation Area and Severity Index (PASI) 0-72 scale
• Skin Discoloration Impact Evaluation Questionnaire (SDIEQ) 0-15 scale
• Dermatology Life Quality Index (DLQI) 0-30 scale
• PROMIS-29 Depression

Photos
• Standard & Cross Polarized Photography Over Time

Patient-Reported Outcomes

Pigmentation Effect on Participant QoL⁴

SDIEQ Score

0-6 Mild effect
7-11 Moderate effect
12-15 Severe effect

SDIEQ 5-Question Scale⁴

1. How embarrassed or self-conscious have you been because of your skin?
2. How much have people focused on your skin discoloration rather than on what you are saying or doing?
3. How much has your skin discoloration made you feel unattractive to others?
4. How much effort have you put into hiding your skin discoloration from others?
5. How much has your skin affected any of your social or leisure activities?

PoSO Impact on HRQoL⁵

DLQI Score

0-1 No effect
2-5 Small effect
6-10 Moderate effect
11-20 Very large effect
21-30 Extremely large effect

Cohorts A+B Comorbidities (N=211)

Diabetes 21.8% Hypertension 63.0% Dyslipidemia 71.6% Metabolic Syndrome* 32.2% PsA 29.9%

Baseline Disease Characteristics Cohort A (N=103) vs Cohort B (N=102)

PASI score (0-72)	20.8 (8.1)	26.8 (19.3)
BSA, %	20.8 (8.1)	26.8 (19.3)
PSSI score (0-72)	34.3 (13.2)	59.8 (26.0)
SSA, %	59.8 (26.0)	59.8 (26.0)

Self-identified Backgrounds and FST in VISIBLE Cohorts A & Cohort B (N=211)

American Indian or Alaska Native	0.5%
Asian	11.4%
Black or African American	44.5%
Hispanic or Latino	44.5%
White	6.2%
Other	14.4%



Self-identified Backgrounds and Fitzpatrick Skin Type

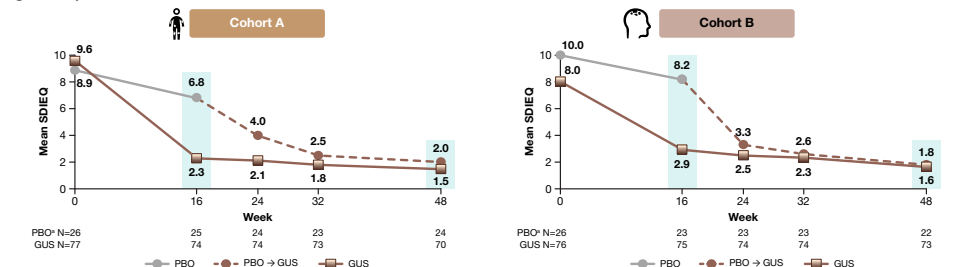
Background	Fitzpatrick Skin Type
Hispanic or Latino (n=93)	I-III
Black or African American (n=102)	III-VI
Asian (n=24)	III-VI
American Indian or Alaska Native (n=1)	I-III
White (n=13)	I-III
Other (n=23)	I-III
Multi-racial (n=1)	III-VI
Hispanic or Latino (n=1)	I-III
Black or African American (n=1)	III-VI
Asian (n=1)	III-VI
American Indian or Alaska Native (n=1)	I-III
White (n=1)	I-III
Other (n=1)	I-III

- VISIBLE recruited a diverse population
- Baseline characteristics show that on average, participants had extensive skin/scale disease and a high comorbidity burden
- 65.9% of participants had a FST in the IV-VI range

RESULTS

- At baseline, participants from both VISIBLE Cohorts A and B reported substantial impact of skin discoloration due to PsO on QoL (mean SDIEQ scores 8-10)
- Rapid and substantial reductions in mean SDIEQ scores were achieved at Weeks 16 and 48, and discontinued to improve through Week 48 consistent with pigment improvement observed in clinical photography

Figure 1. Improvement in mean SDIEQ scores at Weeks 16 and 48



- Overall, there was a stronger correlation between SDIEQ and DLQI scores (Figure 2) vs PASI and DLQI scores (Figure 3) for all skin tones at Week 48
- This effect was more pronounced in the darker skin tone strata (Fitzpatrick IV-VI) for SDIEQ and DLQI scores (r = 0.6826 vs PASI and DLQI scores (r = 0.1789))

Figure 2. Correlation between SDIEQ and DLQI at Week 48

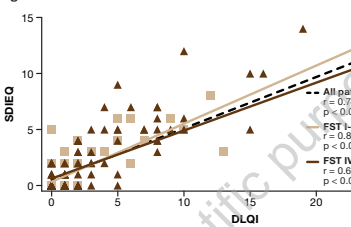
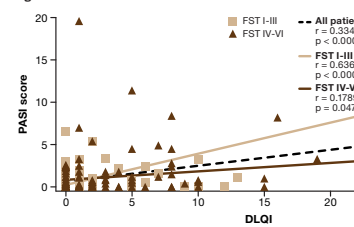


Figure 3. Correlation between PASI and DLQI at Week 48



- This post-hoc analysis showed that PROMIS-29 depression scores were more strongly correlated with SDIEQ scores (Figure 4) than PASI clearance scores (Figure 5) for all skin tones

Figure 4. Correlation between SDIEQ and PROMIS-29 depression score at Week 48: all skin tones

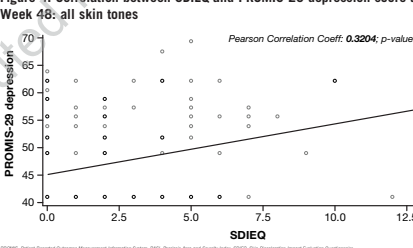
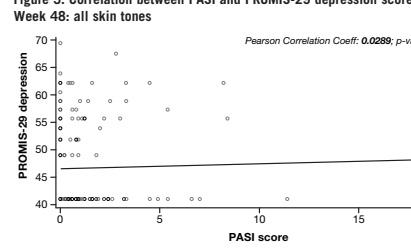
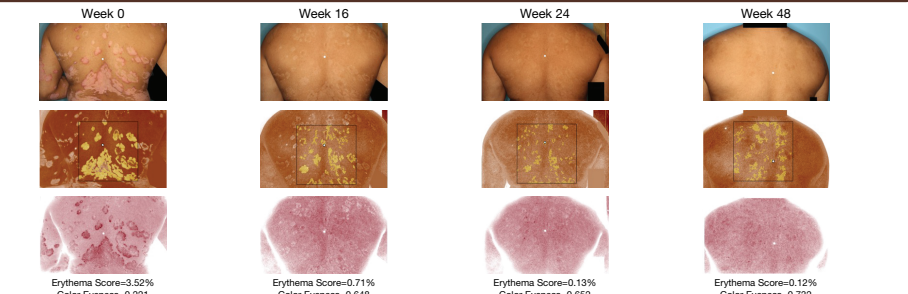


Figure 5. Correlation between PASI and PROMIS-29 depression score at Week 48: all skin tones



Exploratory Analyses: Objective evaluation of cross-polarized photos for erythema, pigmentation, and skin tone evenness over time



CONCLUSIONS

- VISIBLE is a first-of-its-kind prospective study evaluating GUS in participants across all skin tones with moderate-to-severe PsO intentionally designed to collect information on post-inflammatory pigmentation after treatment for PsO
- Substantial, rapid improvements in PIPA, measured by SDIEQ, were reported by participants at Week 16 after 3 doses of GUS, with sustained improvements observed through Week 48 with continued treatment
- SDIEQ is more strongly correlated with DLQI than PASI, which indicates that discoloration is more impactful than skin clearance, especially among darker skin tones, and suggests that PASI outcomes do not adequately measure psoriatic disease burden across all skin tones
- The VISIBLE study demonstrates the importance of capturing standard and cross-polarized photography across skin tones. These photos to inform the various journey types a patient may take and allow for objective analyses to provide insights into PIPA following PsO to showcase and improve patient counseling

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