VISIBLE POST-INFLAMMATORY PIGMENTATION JOURNEYS: EXPLORING THE IMPACT OF PIGMENTATION

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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) in participants **across all skin tones**. VISIBLE was uniquely designed to collect data on post-inflammatory pigment alteration (**PIPA**) through 2 years.
- **PIPA** following resolution of **PsO** plaques is a problem that disproportionately impacts **people of color**.[1,2]
- Among biologic-treated patients with PsO, one survey found that >80% of patients considered **PIPA** to be an important but **neglected problem**.[3]

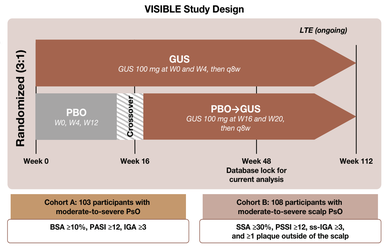
OBJECTIVE/METHODS

Objective

Evaluate impact of PIPA and skin clearance on quality of life (QoL) measures using Skin Discoloration Impact Evaluation Questionnaire (SDIEQ) and Psoriasis Area and Severity Index (PASI) in conjunction with Dermatology Life Quality Index (DLQI), and Patient-Reported Outcomes Measurement Information Systems (PROMIS-29) depression and anxiety

VISIBLE Study Design

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



Cohort A: 103 participants with moderate-to-severe PsO
BSA ≥10%, PASI ≥12, IGA ≥3

Cohort B: 108 participants with moderate-to-severe scalp PsO
SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 plaque outside of the scalp

Cohort A and B Analysis population (N=205)

Outcomes
- Psoriasis Area and Severity Index (PASI)[a]
- Skin Discoloration Impact Evaluation Questionnaire (SDIEQ)[a]
- Dermatology Life Quality Index (DLQI)[b]
- PROMIS-29 Depression and Anxiety[c]

Photos
- Standard & Cross Polarized Photography Over Time

Photo Image Analysis

Color Evenness: algorithm used to objectively evaluate overall variation in color in a defined area taking the rapidity of color change into account. Scores range from a low of 0 (e.g., black and white alternating pixels) to a maximum of 1.0 indicating completely even tone (e.g., white piece of paper)

Patient-Reported Outcomes

Pigmentation Effect on Participant QoL[4]

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

SDIEQ 5-Question Scale[5]

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?

PsO Impact on HRQoL[6]

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

Cohort A & B Comorbidities (N=211)

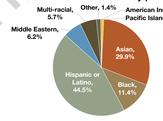
Diabetes	Hypertension	Dyslipidemia	Metabolic Syndrome[a]	PsA
21.8%	63.0%	71.6%	32.2%	29.9%

Baseline Disease Characteristics

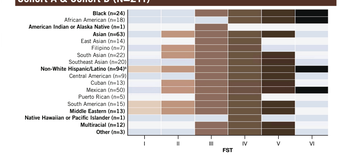
Cohort A (N=103)	
PASI score (0–72)	20.8 (9.1)
BSA, %	26.8 (19.3)
Cohort B (N=102)	
PSSI score (0–72)	34.3 (13.2)
SSA, %	59.8 (26.0)

Data are mean (standard deviation) unless otherwise specified.

Cohort A & B Race/Ethnicity (N=211)



Range of Self-Identified Backgrounds and FST Enrolled in VISIBLE Cohort A & Cohort B (N=211)



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

[a]Scores range from 0–72; higher number indicates increased severity of PsO. [b]Scores range from 0–15; higher number indicates more negative impact. [c]Scores range from 0–30; higher number indicates maximum impact on QoL. [a]Scores for depresssion range from 8 to 40 with higher scores indicating greater severity of depression and scores for anxiety range from 7 to 35 with higher scores indicating greater severity of anxiety. ***BSA***=Body surface area; ***DLQI***=Dermatology Life Quality Index; ***GUS***=Guselkumab; ***IGA***=Investigator Global Assessment; ***LTE***=Long-term extension; ***PASI***=Psoriasis Area and Severity Index; ***PBO***=Placebo; ***PsO***=Psoriasis; ***PROMIS***=Patient-Reported Outcomes Measurement Information System; ***PSSI***=Psoriasis Scalp Severity Index; ***qBw***=Every 8 weeks; ***QoL***=Quality of Life; ***SDIEQ***=Skin Discoloration Impact Evaluation Questionnaire; ***SSA***=Scalp surface area; ***ss-IGA***=Scalp-specific Investigator's Global Assessment; ***W***=Week

[a]Defined as meeting ≥3 of the following criteria at Week 0: BMI ≥30 kg/m², triglycerides ≥150 mg/dL, HDL in men <40 mg/dL or in women <50 mg/dL, BP ≥130/85 mmHg, fasting glucose ≥110 mg/dL. [a]Subcategories shown were reported in ≥5 participants. ***BMI***=Body mass index; ***BP***=Blood pressure; ***BSA***=Body surface area; ***DLQI***=Dematology Life Quality Index; ***HDL***=High density lipoprotein; ***HRQoL***=Health-related quality of life; ***PASI***=Psoriasis Area and Severity Index; ***PsA***=Psoriatic arthritis; ***PsO***=Psoriasis; ***PSSI***=Psoriasis Scalp Severity Index; ***QoL***=Quality of Life; ***SDIEQ***=Skin Discoloration Impact Evaluation Questionnaire; ***SSA***=Scalp surface area

RESULTS

- Mean PASI/PSSI improvement from baseline was ~95% at Week 48 for the GUS-randomized groups (**Figure 1**)
- 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) regardless of skin tone (**Figure 2**)
- Rapid and substantial reductions in mean SDIEQ scores were achieved at Weeks 16 and 48; and continued to improve through Week 48 for both the FST I-III and FST IV-VI cohorts, consistent with clinical photography findings (**Figure 2**)

Figure 1. Improvement in PASI/PSSI at Week 48

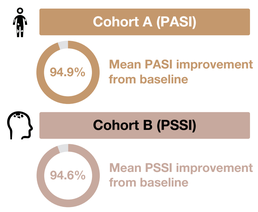
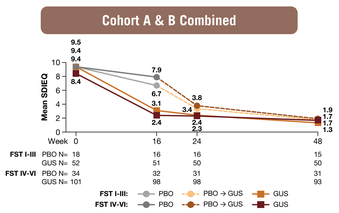


Figure 2. Improvement in mean SDIEQ scores at Weeks 16 and 48 from baseline

Cohort A & B Combined



[a]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 Weeks 24–48. When participants discontinued study agent due to lack of efficacy, worsening of psoriasis, or use of a prohibited PsO treatment, baseline values (at Week 0) were assigned from that point onward. ***FST***=Fitzpatrick Skin Type; ***GUS***=Guselkumab; ***PASI***=Psoriasis Area and Severity Index; ***PBO***=Placebo; ***PsO***=Psoriasis; ***PSSI***=Psoriasis Scalp Severity Index; ***SDIEQ***=Scalp Discoloration Impact Evaluation Questionnaire

- Overall, there was a stronger correlation between SDIEQ and DLQI scores (**Figure 3**) vs PASI and DLQI scores (**Figure 4**) for all skin tones at Week 48; this effect was more pronounced in the darker skin tone strata (FST IV-VI)

Cohort A & B Combined

Figure 3. Correlation between SDIEQ and DLQI at Week 48 by skin tone

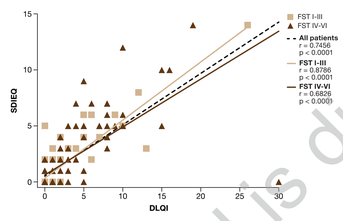
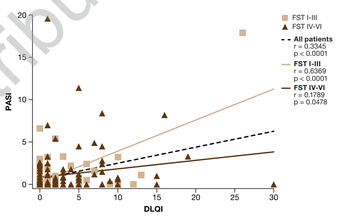
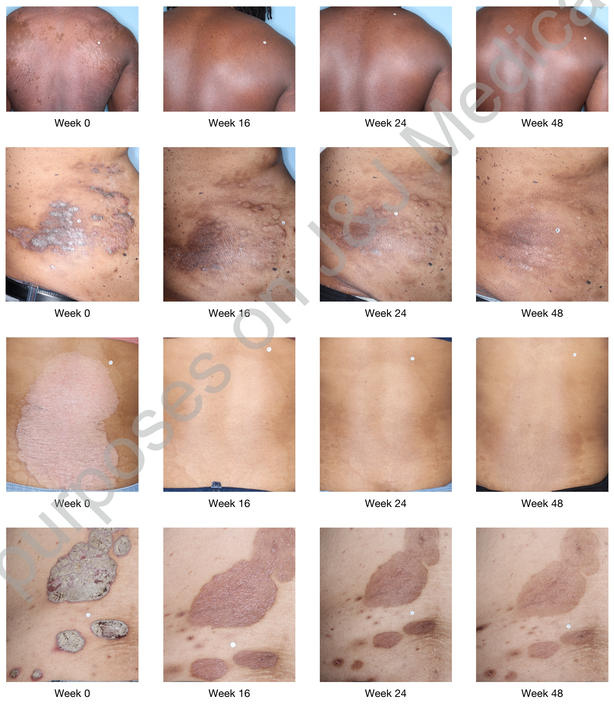


Figure 4. Correlation between PASI and DLQI at Week 48 by skin tone



FST=Fitzpatrick Skin Type; ***DLQI***=Dermatology Life Quality Index; ***PASI***=Psoriasis Area and Severity Index; ***SDIEQ***=Skin Discoloration Impact Evaluation Questionnaire

Post-inflammatory Pigmentation Changes Over Time



- Skin discoloration as measured by SDIEQ correlates with PROMIS-29 depression score (**Figure 5**) whereas there is no correlation between PASI clearance and PROMIS-29 depression score (**Figure 6**) across all skin tones

Cohort A & B Combined

Figure 5. Correlation between SDIEQ and PROMIS-29 depression score at Week 48 by skin tone

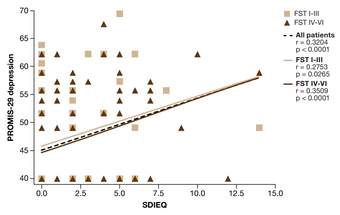
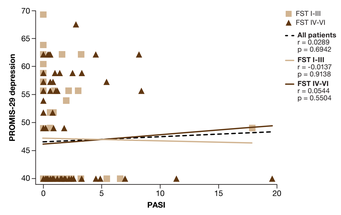


Figure 6. Correlation between PASI and PROMIS-29 depression score at Week 48 by skin tone



FST=Fitzpatrick Skin Type; ***PASI***=Psoriasis Area and Severity Index; ***PROMIS***=Patient-Reported Outcomes Measurement Information System; ***SDIEQ***=Skin Discoloration Impact Evaluation Questionnaire

- Skin discoloration as measured by SDIEQ correlates with PROMIS-29 anxiety score (**Figure 7**) whereas PASI clearance does not correlate with anxiety score (**Figure 8**) in this post-hoc analysis across all skin tones

Cohort A & B Combined

Figure 7. Correlation between SDIEQ and PROMIS-29 anxiety score at Week 48 by skin tone

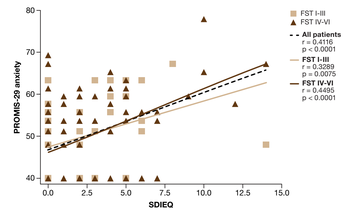
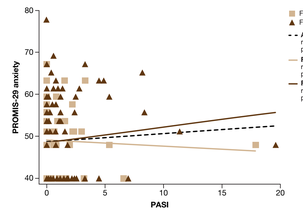
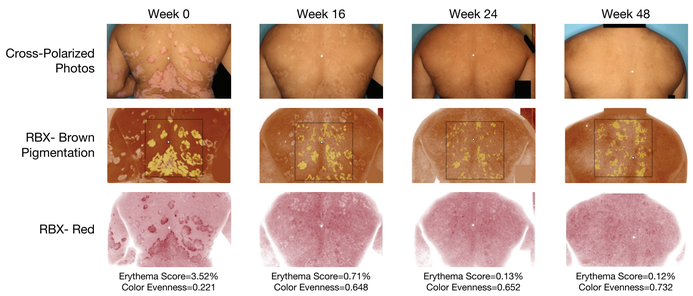


Figure 8. Correlation between PASI and PROMIS-29 anxiety score at Week 48 by skin tone



FST=Fitzpatrick Skin Type; ***PASI***=Psoriasis Area and Severity Index; ***PROMIS***=Patient-Reported Outcomes Measurement Information System; ***SDIEQ***=Skin Discoloration Impact Evaluation Questionnaire

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



RBX=Red, Brown, Xanth

CONCLUSIONS

VISIBLE is a first-of-its-kind study dedicated 100% to participants of all skin tones with moderate-to-severe PsO intentionally designed to examine post-inflammatory pigmentation after resolution of PsO

PIPA has high impact on QoL, depression, and anxiety, more so than clearance measured by PASI, suggesting that clinicians should proactively and better counsel on PIPA

The photos and data from VISIBLE may allow for objective analyses to provide additional insights into PIPA that may inform and improve patient counseling

References: 1. Amico S, et al. *J Am Acad Dermatol.* 2020;83:1188-1191. **2.** Kaufman BP, et al. *Am J Clin Dermatol.* 2018;19:405-423. **3.** Chiu HY, et al. *J Am Acad Dermatol.* 2022;86:642-645. **4.** Maymone MBC, et al. *J Dermatol.* 2018;45:361-2. **5.** Balkrishnan R, et al. *J Drugs Dermatol.* 2004;3:377-381. **6.** Hongbo Y, et al. *J Invest Dermatol.* 2005;125:659-664.

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