VISIBLE (COHORT B): GUSELKUMAB DEMONSTRATES COMPARABLE 1-YEAR EFFICACY IN MODERATE-TO-SEVERE SCALP PSORIASIS PARTICIPANTS WITH HIGH VS LOW BASELINE BODY SURFACE AREA INVOLVEMENT

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BACKGROUND

Scalp involvement is common, burdensome, and often the first special site affected in individuals **with psoriasis (PsO)**[1]

Because individuals with **moderate-to-severe scalp PsO** and low total **body surface area** (BSA) involvement are infrequently treated with systemic therapy,[2] more data are needed in this **under-treated population** to help inform treatment considerations

VISIBLE is an ongoing, Phase 3b, randomized, placebo (PBO)-controlled study 100% dedicated to **people of color,** with **Cohort B** comprised of participants with moderate-to-severe **scalp PsO** across all skin tones

BACKGROUND/METHODS

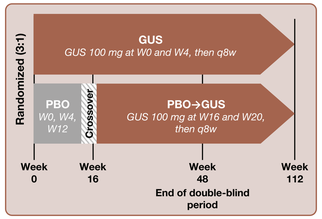
Objective

Evaluate GUS efficacy in VISIBLE Cohort B participants with moderate-to-severe scalp PsO and high vs low BSA involvement

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[a] with moderate-to-severe scalp PsO
SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 plaque outside of the scalp



Physician-reported Outcomes

- **Scalp-specific Investigator Global Assessment (ss-IGA) range 0-4**
- **Psoriasis Scalp Severity Index (PSSI) range: 0-72**
- **Scalp Surface Area of disease (SSA) range: 0-100%**

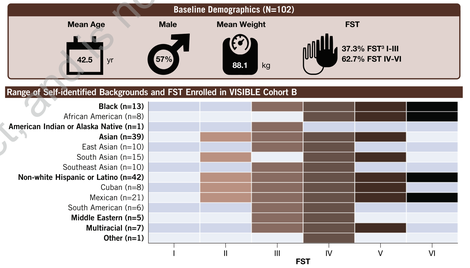
Definition of Low and High BSA Groups

Baseline BSA (%) and Investigator Global Assessment

- **Low BSA Involvement:** BSA ≥2% to <10% and IGA=3
- **High BSA Involvement:** BSA ≥10% and IGA 3 or 4

PASI=Psoriasis Area and Severity Index; q8h=Every 8 weeks; W=Week. [a]Efficacy analysis population included all participants correctly randomized to Cohort B (n=102).

RESULTS: VISIBLE COHORT B



Although the low BSA group had less extensive PsO overall, the low and high BSA groups had moderate-to-severe scalp disease at baseline

Table 1. Baseline Disease Characteristics

	Low BSA (BSA ≥2% to 10%)	High BSA (BSA >10%)
Analysis set, n	33	62
Psoriasis duration, yr	10.4 (9.6)	12.0 (11.4)
ss-IGA, n (%)		
3 Moderate	33 (100.0)	46 (74.2)
Severe	0	16 (25.8)
PSSI (0-72)	29.1 (9.8)	36.6 (13.9)
SSA, %	53.1 (24.8)	62.4 (26.1)
IGA, n (%)		
3 Moderate	33 (100.0)	46 (74.2)
Severe	0	16 (25.8)
PASI (0-72)	7.1 (3.4)	19.3 (8.9)
BSA, %	6.1 (1.7)	23.2 (14.9)

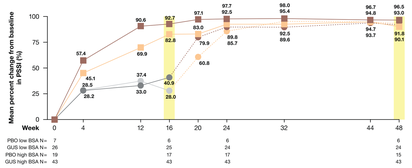
FST=Fitzpatrick Skin Type; SD=Standard deviation. Subcategories shown were reported in >5 participants. Data shown are mean (SD) unless otherwise indicated.

RESULTS

Scalp Measures

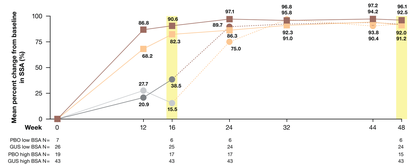
At Week 48, GUS-randomized participants with high/low BSA achieved comparable high rates of scalp clearance: mean percent improvement from baseline in PSSI, 96.5%/90.1%, respectively (Figure 1)

Figure 1. Mean percent improvement from baseline in PSSI score through Week 48



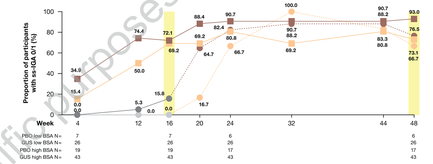
At Week 48, GUS-randomized participants with high/low BSA achieved comparable high rates of scalp clearance: mean percent improvement from baseline in SSA 96.1%/91.2%, respectively (Figure 2)

Figure 2. Mean percent improvement from baseline in SSA score through Week 48



Absent/minimal scalp disease assessed via ss-IGA 0/1 was achieved by 93.0%/73.1% of GUS-randomized participants with high/low baseline BSA, respectively at Week 48 (Figure 3)

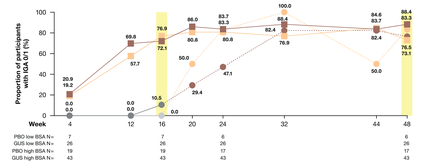
Figure 3. Proportion of participants achieving complete/almost complete scalp clearance through Week 48



Skin Measures

With respect to skin disease, IGA 0/1 was achieved by 88.4%/73.1% of GUS-randomized participants with high/low BSA, respectively at Week 48 (Figure 4)

Figure 4. Proportion of participants achieving clear/almost clear skin through Week 48



At Week 48, GUS-randomized participants with high/low BSA achieved comparable high rates of skin clearance: mean percent improvement from baseline in PASI, 95.8%/90.9%, respectively (Figure 5)

Figure 5. Mean percent improvement from baseline in PASI score through Week 48

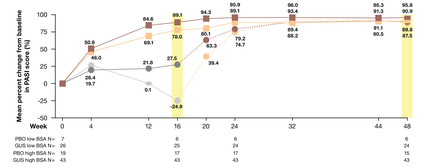


Figure 6. Low BSA Participant With 100% SSA Involvement at Baseline Who Achieved Complete Scalp Clearance at Weeks 16 and 48

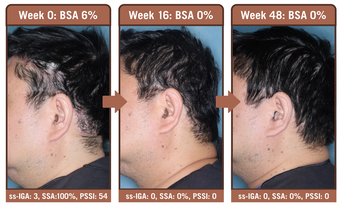
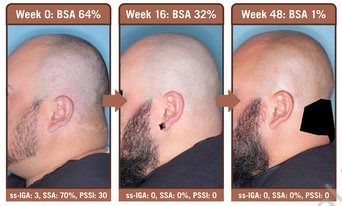
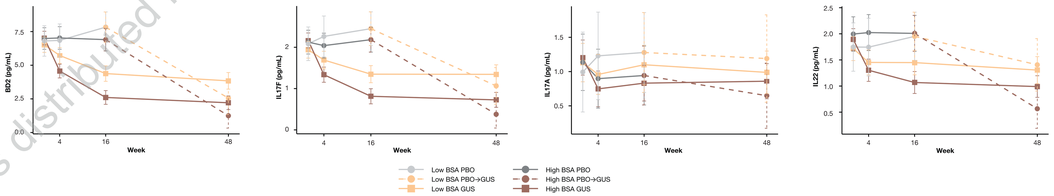


Figure 7. High BSA Participant Who Achieved Complete Scalp Clearance at Weeks 16 and 48



Greater responses in serum levels of cytokines associated with psoriasis were seen in high- vs low-BSA participants (Figure 8)

Figure 8. Serum beta-defensin 2 (BD2), interleukin (IL)-17F, IL-17A, and IL-22 responses



CONCLUSIONS

- **VISIBLE is a first-of-its-kind study intentionally designed to evaluate the safety and efficacy of GUS in moderate-to-severe PsO across all skin tones, with Cohort B dedicated to participants with moderate-to-severe scalp PsO**
- **GUS-treated participants achieved generally comparable scalp and skin clearance at Week 48 whether participants had low or high baseline BSA involvement, providing clinicians and patients across all skin tones with an effective treatment option for those with scalp PsO regardless of baseline BSA**
- **Future biomarker studies will further investigate the relationship between clinical response and the underlying disease biology**

References: 1. Wang T-S et al. *Am J Clin Dermatol.* 2017;18:17–43. **2.** Merola JF et al. *Dermatol Ther.* 2018;31: e12589. doi: 10.1111/dth.12589. **3.** Fitzpatrick TB. *Arch Dermatol.* 1988;124:869-71.

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