VISIBLE COHORT B: GUSELKUMAB DEMONSTRATES SIGNIFICANT SCALP CLEARANCE AT WEEK 16 IN PARTICIPANTS WITH MODERATE-TO-SEVERE SCALP PSORIASIS ACROSS ALL SKIN TONES

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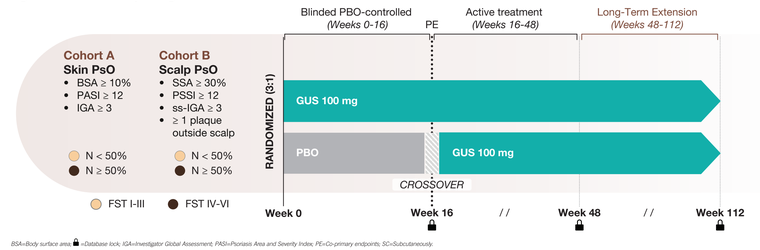
BACKGROUND/OBJECTIVE

- Scalp psoriasis (PsO) can cause great physical and social distress, with up to 97% of affected individuals reporting that it interferes with their daily life[1]
- Scalp PsO is often associated with intense pruritus and scaling. In some cases, it can even result in alopecia which, in most cases, is reversible with appropriate treatment.[2]
- VISIBLE is an ongoing, first-of-its kind, large-scale, prospective, Phase 3b, randomized, double-blind, placebo (PBO)-controlled study designed to evaluate the efficacy and safety of guselkumab (GUS) in patients of color across all skin tones, with a cohort specifically dedicated to moderate-to-severe scalp PsO
- The VISIBLE study population is comprised of two cohorts, Cohort A and Cohort B (see **Figure 1**); results for Cohort B are presented in this analysis
- **To evaluate the impact of GUS treatment vs PBO on efficacy (scalp-specific Investigator Global Assessment [ss-IGA] score, Psoriasis Scalp Severity Index [PSSI], Scalp Surface Area [SSA]) at Week 16 and safety in participants with moderate-to-severe scalp PsO across all skin tones**

METHODS

Figure 1. VISIBLE Study Design



BSA=Body surface area; 🔒=Database lock; IGA=Investigator Global Assessment; PASI=Psoriasis Area and Severity Index; PE=Co-primary endpoints; SC=Subcutaneously.

- Co-Primary Endpoints at Week 16
  - **Cohort A** PASI 90 & IGA 0/1
  - **Cohort B** PSSI 90 & ss-IGA 0/1
- Key Inclusion Criteria: ≥18 years of age, self-identification as non-white
  - All Fitzpatrick Skin Types (FST) I-VI,[3] as determined by colorimetry, were eligible
- In Cohort B, 108 participants were randomized 3:1 to receive GUS SC or PBO at Weeks 0, 4, then every 8 weeks
- The efficacy analysis population included all participants who were correctly randomized to Cohort B (n=102); safety was evaluated for all randomized participants (n=108)

BASELINE DEMOGRAPHICS

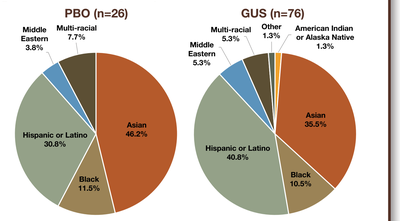
Baseline demographics were generally balanced between the GUS and PBO groups for participants across all skin tones

Table 1. Baseline Demographics: Cohort B

	PBO	GUS	Total
Efficacy analysis set, n	26	76	102
Age (years)	41.1 (13.1)	42.9 (13.9)	42.5 (13.6)
Male, n (%)	18 (69.2%)	40 (52.6%)	58 (56.9%)
BMI (kg/m²)	28.3 (6.3)	31.6 (8.2)	30.8 (7.9)
Weight (kg)	82.5 (19.7)	90.0 (25.0)	88.1 (23.9)
FST Strata, n (%)			
I-III	10 (38.5%)	28 (36.8%)	38 (37.3%)
IV-VI	16 (61.5%)	48 (63.2%)	64 (62.7%)
PsO disease duration (years)	11.3 (12.8)	11.3 (9.8)	11.3 (10.6)
Age at diagnosis (years)	29.8 (16.0)	31.7 (15.0)	31.2 (15.2)
Participants with psoriatic arthritis, n (%)[a]	6 (23.1%)	22 (28.9%)	28 (27.4%)

BMI=Body mass index; SD=Standard deviation. Data shown are mean (SD), unless otherwise indicated. [a]Psoriatic arthritis participants are those who are rheumatologist confirmed or PEST positive at screening.

Figure 2. Race/Ethnicity Composition



CONCLUSIONS

- **After just 3 doses of GUS, the majority of participants achieved rapid and significant scalp clearance across all measures evaluated, with nearly 6 of 10 achieving complete scalp clearance at Week 16**
- **These results highlight that GUS is a highly effective treatment for extensive moderate-to-severe scalp PsO and will enable evidence-based shared decision-making for people with scalp PsO across diverse populations and the full range of skin tones**

~70% — of participants achieved a clear/minimal scalp PsO response (ss-IGA 0/1)

>80% — mean % improvement in PSSI and SSA after 3 doses

CLEAR ss-IGA 0 PSSI 100 — ~60% of participants achieved complete clearance of scalp PsO after 3 doses

11.6 Weeks — median time to achieve PSSI 90 response

Figure 3. Efficacy in a Participant Self-Identifying as Black, FST VI

ss-IGA: 4, PSSI: 72, SSA: 100 — ss-IGA: 0, PSSI: 0, SSA: 0

Photos are from a consenting participant during the blinded phase of the VISIBLE Study.

RESULTS

Disease severity, as measured by ss-IGA, PSSI, and SSA, reflect extensive moderate-to-severe scalp disease

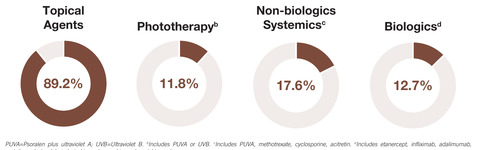
Table 2. Disease Characteristics: Cohort B

	PBO	GUS	Total
Efficacy analysis set, n	26	76	102
ss-IGA, n (%)			
Moderate (3)	20 (76.9%)	64 (84.2%)	84 (82.4%)
Severe (4)	6 (23.1%)	12 (15.8%)	18 (17.6%)
PSSI (0-72)	34.0 (11.8)	34.4 (13.7)	34.3 (13.2)
SSA (%)	56.6 (22.4)	60.8 (27.1)	59.8 (26.0)
IGA, n (%)			
Minimal (1)	0	1 (1.3%)	1 (1.0%)
Mild (2)	0	3 (3.9%)	3 (2.9%)
Moderate (3)	19 (73.1%)	60 (78.9%)	79 (77.5%)
Severe (4)	7 (26.9%)	12 (15.8%)	19 (18.6%)
PASI (0-72)	17.1 (8.2)	13.7 (9.6)	14.6 (9.3)
BSA (%)	19.1 (12.1)	15.7 (15.0)	16.6 (14.4)

Data shown are mean (SD), unless otherwise indicated.

Despite the high degree of disease severity, <20% of participants had any previous exposure to systemic therapy (proportions of participants receiving prior phototherapy, non-biologic systemics, and biologics were 11.8%, 17.6%, and 12.7%, respectively)

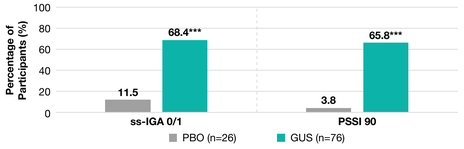
Figure 4. Previous PsO Medications/Therapies: Cohort B



PUVA=Psoralen plus ultraviolet A; UVB=Ultraviolet B. [b]Includes PUVA or UVB. [c]Includes PUVA, methotrexate, cyclosporine, acitretin. [d]Includes etanercept, infliximab, adalimumab, certolizumab, bimdalumab, ixekizumab, secukinumab, ustekinumab.

Significantly greater proportions of participants in the GUS group achieved the co-primary endpoints compared to the PBO group at Week 16

Figure 5. Co-Primary Endpoints: ss-IGA 0/1 and PSSI 90 at Week 16

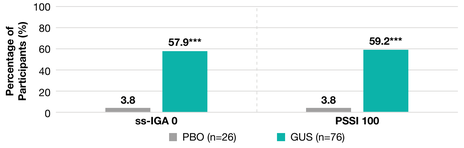


***p<0.001 vs PBO. CMH=Cochran-Mantel-Haenszel. p-values are based on CMH test stratified by FST (Type I-III/Type IV-VI). Non-responder imputation was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to Week 16 were considered non-responders. Participants with missing data were considered non-responders.

- Median time to achieve PSSI 90 response for the GUS group was 11.6 weeks (vs not achieved for the PBO group)

A majority of participants in the GUS group achieved complete scalp clearance (ss-IGA 0 and PSSI 100) compared to the PBO group at Week 16

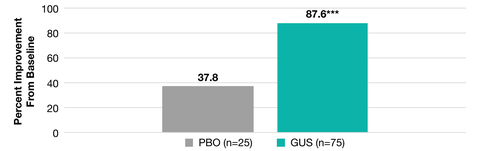
Figure 6. Major Secondary Endpoints: ss-IGA 0 and PSSI 100 at Week 16



***p<0.001 vs PBO. p-values are based on CMH test stratified by FST (Type I-III/Type IV-VI). Non-responder imputation was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to Week 16 were considered non-responders. Participants with missing data were considered non-responders.

Significantly greater mean percent improvement from baseline PSSI was observed in the GUS group vs the PBO group at Week 16

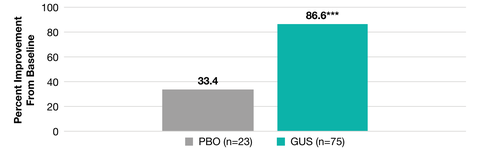
Figure 7. Major Secondary Endpoint: Percent Improvement From Baseline (LS Mean) PSSI at Week 16



***p<0.001 vs PBO. LSMeans=Least Squares Means; MMRM=Mixed-Effect Model Repeated Measures. LSMeans and p-value were based on MMRM. Zero change was assigned for participants who discontinued study agent due to lack of efficacy; worsening of PsO; or initiated a prohibited PsO treatment prior to Week 16. Missing data were handled by MMRM under missing at random assumption.

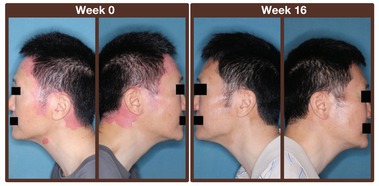
Significantly greater mean percent improvement from baseline SSA was observed in the GUS group vs the PBO group at Week 16

Figure 8. Major Secondary Endpoint: Percent Improvement From Baseline (LS Mean) SSA at Week 16



***p<0.001 vs PBO. LSMeans and p-value were based on MMRM. Zero change was assigned for participants who discontinued study agent due to lack of efficacy, worsening of PsO, or initiated a prohibited PsO treatment prior to Week 16. Missing data were handled by MMRM under missing at random assumption.

Figure 9. Efficacy in a Participant Self-Identifying as Asian, FST III



ss-IGA: 3, PSSI: 42, SSA: 100 — ss-IGA: 0, PSSI: 0, SSA: 0

Photos are from a consenting participant during the blinded phase of the VISIBLE Study.

Table 3. Key Safety Information Through Week 16: Cohort B

	PBO	GUS
Safety analysis set, n	27	81
Average duration of follow-up (weeks)	15.4	16.2
≥1 AE	3 (11.1%)	29 (35.8%)
Discontinued due to ≥1 AE	0	0
≥1 SAE	1 (3.7%)	0
≥1 Injection site reactions	0	1 (1.2%)
Infections	1 (3.7%)	12 (14.8%)
Serious infections	1 (3.7%)	0
Malignancies (including NMSC)	0	0
Active TB	0	0
IBD	0	0
MACE	0	0
Deaths	0	0

AE=Adverse events; IBD=Inflammatory bowel disease; MACE=Major adverse cardiovascular events; NMSC=Nonmelanoma skin cancer; SAE=Serious adverse events; TB=Tuberculosis. Data shown are n (%), unless otherwise indicated. Participants are counted only once for any given event, regardless of the number of times they actually experienced the event. Adverse events are coded using MedDRA version 25.1.

- Safety outcomes were consistent with the established GUS safety profile and no new safety signals were identified

References

1. Crowley J. *J Drugs Dermatol.* 2010;9:912-8.
2. George SMC, et al. *Clin Exp Dermatol.* 2015;40:717-21.
3. Fitzpatrick TB. *Arch Dermatol.* 1988;124:869-71.

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