VISIBLE COHORT B: GUSELKUMAB DEMONSTRATED SCALP CLEARANCE AND IMPROVED HEALTH-RELATED QUALITY OF LIFE THROUGH WEEK 48 IN PARTICIPANTS WITH MODERATE-TO-SEVERE SCALP PSORIASIS ACROSS ALL SKIN TONES

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BACKGROUND/OBJECTIVE

VISIBLE is an ongoing Phase 3b, multicenter, randomized, double-blinded, placebo (PBO)-controlled study of guselkumab (GUS) for the treatment of participants with moderate-to-severe plaque psoriasis (PsO) across all skin tones

VISIBLE is comprised of 2 cohorts:

- **Cohort A:** participants with moderate-to-severe plaque PsO
- **Cohort B:** participants with moderate-to-severe scalp PsO

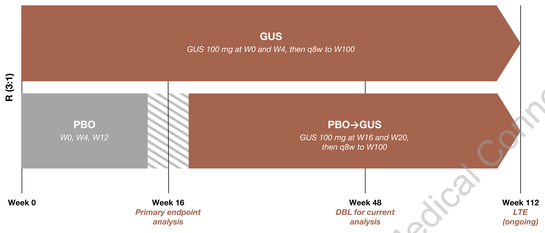
VISIBLE evaluated the efficacy and safety of GUS for treating scalp PsO in Cohort B participants through Week 48

METHODS

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

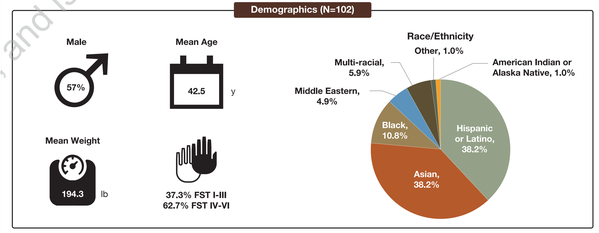
Cohort B: 108 participants[a] with moderate-to-severe scalp PsO
SSA ≥30%, PSSI ≥12, ss-IGA ≥3,
≥1 plaque outside of the scalp



[a]Efficacy was assessed in all participants who met Cohort B inclusion criteria (N=103). BSA=Body surface area; DBL=Database lock; IGA=Investigator's Global Assessment; LTE=Long-term extension; PASI=Psoriasis Area and Severity Index; PSSI=Psoriasis Scalp Severity Index; q8w=Every 8 weeks; R=Randomized; SSA=Scalp surface area; ss-IGA=Scalp-specific–Investigator's Global Assessment; W#=Week.

COHORT B BASELINE CHARACTERISTICS

Demographics (N=102)



FST=Fitzpatrick skin type.

Disease Characteristics

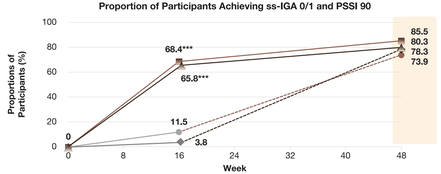
	PBO (N=26)	GUS (N=76)
PsO Duration, y	11.3 (12.8)	11.3 (9.8)
ss-IGA, n (%)		
Moderate 3	20 (76.9)	64 (84.2)
Severe 4	6 (23.1)	12 (15.8)
PSSI (0-72)	34.0 (11.8)	34.4 (13.7)
SSA, %	56.6 (22.4)	60.8 (27.1)
PSSD (0-100)	67.8 (20.1)	61.9 (24.7)

Mean (standard deviation) unless otherwise noted. PSSD=Psoriasis Symptoms and Signs Diary.

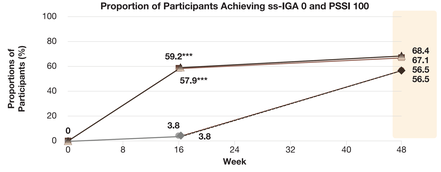
RESULTS

Significantly greater proportions of GUS-randomized vs PBO-randomized participants achieved ss-IGA and PSSI endpoints at Week 16, and response rates were sustained or increased at Week 48

Proportion of Participants Achieving ss-IGA 0/1 and PSSI 90



Proportion of Participants Achieving ss-IGA 0 and PSSI 100



Week 0

ss-IGA 3
PSSI 42
SSA 100%

Week 16

ss-IGA 1
PSSI 7
SSA 1%
ΔPSSI 83.3%
ΔSSA 99.0%

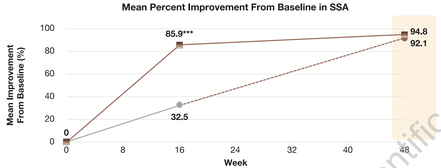
Week 48

ss-IGA 0
PSSI 0
SSA 0%
ΔPSSI 100%
ΔSSA 100%

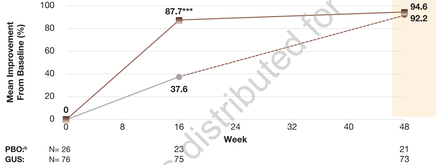
***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel test stratified by FST (I-III/IV-VI). [a]For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included at Week 48. Participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered non-responders from that point forward. Participants with missing data were considered non-responders at that time point. Δ=Mean improvement.

Among GUS-randomized participants, mean percent improvement in SSA and PSSI was >85% at Week 16 and increased to ~95% at Week 48

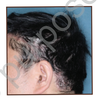
Mean Percent Improvement From Baseline in SSA



Mean Percent Improvement From Baseline in PSSI



Week 0



ss-IGA 3
PSSI 54
SSA 100%

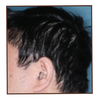
ss-IGA 4
PSSI 72
SSA 100%

Week 16

ss-IGA 0
PSSI 0
SSA 0%
ΔPSSI 100%
ΔSSA 100%

ss-IGA 0
PSSI 0
SSA 0%
ΔPSSI 100%
ΔSSA 100%

Week 48



ss-IGA 0
PSSI 0
SSA 0%
ΔPSSI 100%
ΔSSA 100%

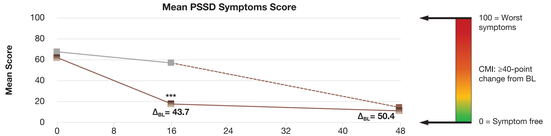
ss-IGA 0
PSSI 0
SSA 0%
ΔPSSI 100%
ΔSSA 100%

***p<0.001 vs PBO; p-values were based on the mixed-effect model for repeated measures (MMRM). [a]For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. When participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, 0 change from baseline was assigned from that point onward. Missing data were not imputed.

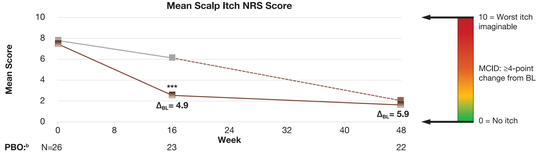
Among GUS-randomized participants, the overall PSSD Symptoms Score and the Scalp Itch Numeric Rating Scale (NRS) Score showed significant mean improvements from baseline at Week 16, which were maintained at Week 48

- The proportion of GUS-randomized participants achieving an overall PSSD Symptoms Score of 0[c] increased from 21% at Week 16 to 35% at Week 48, and the proportion achieving ≥4-point improvement from baseline in the Scalp Itch NRS Score[d] increased from 69% to 81%

Mean PSSD Symptoms Score



Mean Scalp Itch NRS Score



***p<0.001 vs PBO; p-value was based on the MMRM for PSSD Symptoms Score and analysis of covariance for Scalp Itch NRS Score. When participants discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, 0 change from baseline was assigned from that point onward. Missing data were not imputed. [a]For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. [b]GUS-randomized participants with baseline PSSD Symptoms Score ≥1. [c]Participants with baseline PSSD Itch Symptom Score ≥4. Participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered non-responders from that point forward. Participants with missing data were considered non-responders at that time point. BL=Baseline; CMI=Clinically meaningful improvement. MCID=Minimal clinically important difference. SBL=Mean improvement from baseline.

Key Safety Information

	PBO→GUS* (Weeks 16-48)	GUS (Weeks 0-48)
Safety analysis set, N	24	81
Average duration of follow-up (weeks)	31.1	47.7
Participants with ≥1 AE	9 (37.5)	51 (63.0)
Participants with ≥1 AE leading to discontinuation of study agent	0	0
Participants with ≥1 SAE	0	2 (2.5)[f]
Participants with ≥1 injection-site reaction	0	1 (1.2)
Infections	4 (16.7)	27 (33.3)
Serious infections	0	0

Data shown are n (%), unless otherwise indicated. *Includes only PBO participants who crossed over to receive GUS. [f]The SAEs in GUS-treated participants were 1 event each of angina pectoris and pancreatitis. Participants were counted only once for any given event, regardless of the number of times they experienced the event. AEs were coded using MedDRA version 25.1. AE=Adverse event; SAE=Serious adverse event.

- Through Week 48, there were no cases of death, malignancy, active tuberculosis, major adverse cardiac event, inflammatory bowel disease, or serum-like sickness or anaphylaxis

CONCLUSIONS

At Week 48, among GUS-randomized participants in Cohort B of the VISIBLE study:

- >80% achieved absent/very mild scalp disease (ss-IGA 0/1, PSSI 90), and >65% achieved complete scalp clearance (ss-IGA 0, PSSI 100)
- mean percent improvement from baseline in SSA and PSSI was ~95%
- clinically meaningful improvements in the mean overall PSSD Symptoms Score and the mean Scalp Itch NRS Score were achieved

No new safety signals were identified

These results demonstrate that GUS is a highly effective and durable treatment for moderate-to-severe scalp PsO in participants across all objectively measured skin tones, with sustained or improved responses through Week 48

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