VISIBLE COHORT A: GUSELKUMAB DEMONSTRATED SKIN CLEARANCE AND IMPROVED HEALTH-RELATED QUALITY OF LIFE THROUGH WEEK 48 IN PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE 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

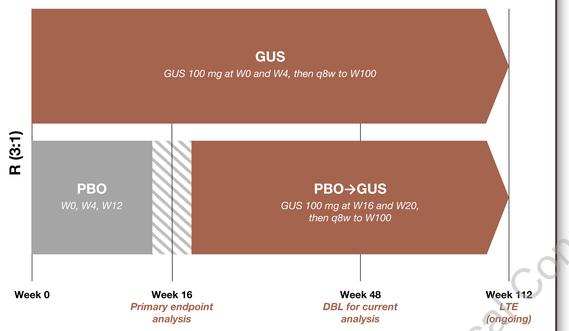
VISIBLE evaluated the efficacy and safety of GUS in Cohort A participants through Week 48

METHODS

Included participants who self-identified as non-white, across all objectively measured skin tones

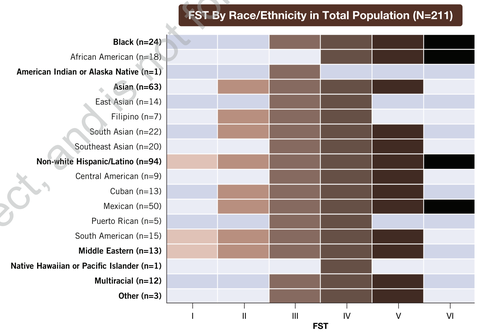
Cohort A: 103 participants with moderate-to-severe plaque PsO
BSA ≥10%, PASI ≥12, IGA ≥3

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



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.

BASELINE CHARACTERISTICS



FST=Fitzpatrick skin type.

Cohort A Demographics (N=103)

Male	Mean Age	Mean Weight	
72%	44.1 y	209 lb	31.1% FST I-III 68.9% FST IV-VI

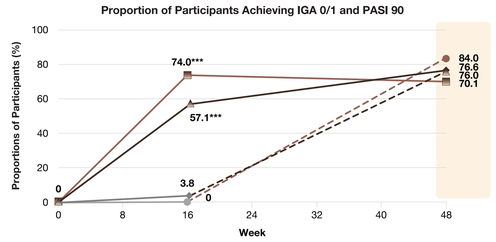
Cohort A Baseline Disease Characteristics

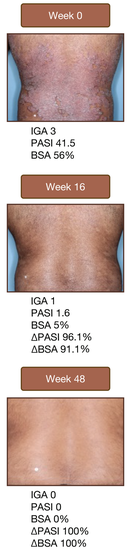
	PBO (N=26)	GUS (N=77)
PsO Duration, y	14.9 (8.8)	14.9 (11.0)
ss-IGA, n (%)		
Moderate [3]	21 (80.8)	57 (74.0)
Severe [4]	5 (19.2)	20 (26.0)
PSSI (0-72)	19.8 (6.2)	21.2 (9.9)
BSA, %	26.1 (15.9)	27.0 (20.4)
PSSD (0-100)	61.8 (27.0)	66.1 (25.0)

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

RESULTS

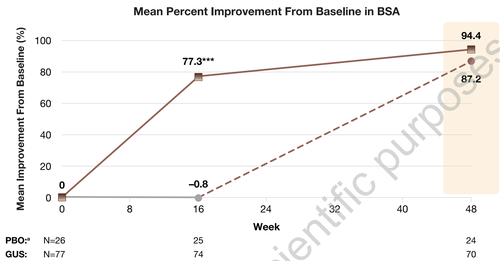
Significantly greater proportions of GUS-randomized vs PBO-randomized participants achieved IGA and PASI endpoints at Week 16, and response rates were sustained or increased at Week 48

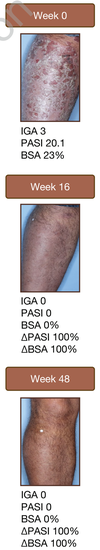




**p<0.01 vs PBO; ***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel test stratified by FST (I-II/III-VI). aFor participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included at Week 48. Participants who discontinued study agent 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 BSA and PASI was >77% at Week 16 and increased to ~95% at Week 48

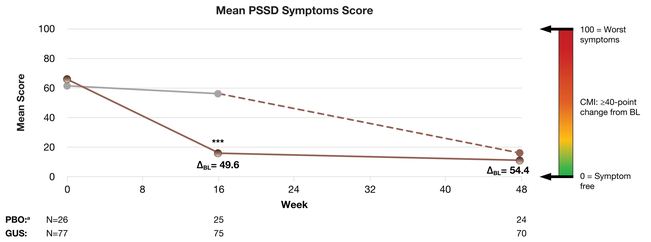




***p<0.001 vs PBO; p-values were based on the mixed-effect model for repeated measures (MMRM). aFor participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. When participants who discontinued study agent due to lack of efficacy, worsening 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 PSSD Itch Symptom 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[a] increased from 10% at Week 16 to 23% at Week 48, and the proportion achieving ≥4-point improvement from baseline in the PSSD Itch Symptom Score[b] was durable



***p<0.001 vs PBO; p-values were based on the MMRM. 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. aFor participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. bGUS-randomized participants with baseline PSSD Symptoms Score ≥1. cParticipants 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; ΔBL=Mean improvement from baseline.

Key Safety Information

	PBO→GUS[a] (Weeks 16-48)	GUS (Weeks 0-48)
Safety analysis set, N	25	77
Average duration of follow-up (weeks)	31.5	46.3
Participants with ≥1 AE	5 (20.0)	48 (62.3)
Participants with ≥1 AE leading to discontinuation of study agent	0	2 (2.6)[e]
Participants with ≥1 SAE	1 (4.0)[f]	1 (1.3)[g]
Participants with ≥1 injection-site reaction	0	0
Infections	5 (20.0)	28 (36.4)
Serious infections	1 (4.0)[f]	1 (1.3)[g]

Data shown are n (%), unless otherwise indicated. aIncludes only PBO participants who crossed over to receive GUS. bAEs leading to discontinuation among GUS-treated participants were 1 event each of pregnancy and impetigoid atopic dermatitis. cThe SAE in a PBO-GUS participant was 1 event of cellulitis. dThe SAE in a GUS-treated participant was 1 event of pyelonephritis. 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 A of the VISIBLE study:

- >70% achieved clear/almost clear skin (IGA 0/1, PASI 90), and >50% achieved complete skin clearance (IGA 0, PASI 100)
- mean percent improvement from baseline in BSA and PASI was ~95%
- clinically meaningful improvements in the mean overall PSSD Symptoms Score and the mean PSSD Itch Symptom 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 plaque PsO in participants across all objectively measured skin tones, with sustained or improved responses through Week 48

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