VISIBLE: GUSELKUMAB DEMONSTRATED SIGNIFICANT SCALP PSORIASIS CLEARANCE AND SCALP ITCH IMPROVEMENTS AT WEEK 16 IN SKIN OF COLOR PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

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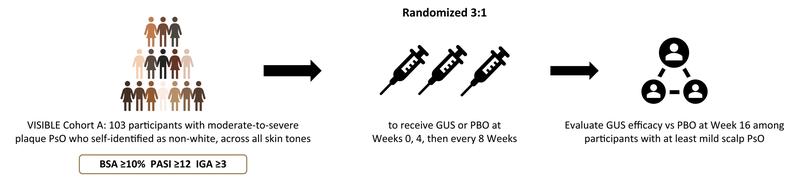
BACKGROUND/OBJECTIVE

- Scalp is the most commonly involved special site among patients with moderate-to-severe plaque psoriasis (PsO) and may be challenging to treat in skin of color patients due to greater visibility of scales and styling/hair types
- VISIBLE is a first-of-its-kind, large-scale, prospective, Phase 3b, randomized, double-blind, placebo (PBO)-controlled study dedicated to participants with moderate-to-severe plaque PsO across all skin tones
- **We report the efficacy of guselkumab (GUS) on scalp PsO in the Phase 3b VISIBLE study (Cohort A), which exclusively enrolled skin of color participants with moderate-to-severe plaque PsO**

METHODS

VISIBLE Study Design



BSA=body surface area; GUS=guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=placebo; PsO=psoriasis.

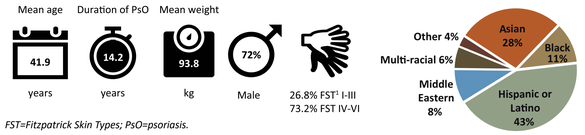
CONCLUSIONS

GUS treatment resulted in substantial and rapid improvements in scalp PsO among participants with diverse skin tones who had at least mild scalp PsO at baseline

- **>50% PSSI improvement** — **>50% mean improvement in PSSI after just 1 dose of GUS**
- **CLEAR ss-IGA 0** — **The majority of participants achieved complete clearance after 2 doses of GUS**
- **↓SSA** — **Substantial reduction in % SSA involved with disease after 3 doses of GUS**
- **↓Itch** — **Clinically meaningful reduction from baseline in Scalp Itch NRS score after 3 doses of GUS**

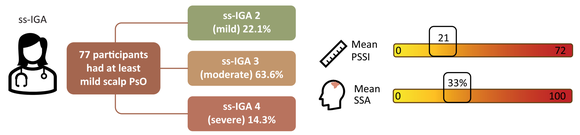
RESULTS

Baseline demographics of those patients with scalp PsO measures at baseline (total, n=82)

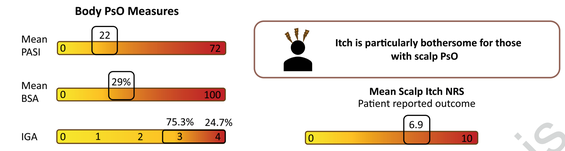


FST=Fitzpatrick Skin Types; PsO=psoriasis.

Baseline scalp PsO measures of those patients with ss-IGA ≥2 at baseline (total, n=77)



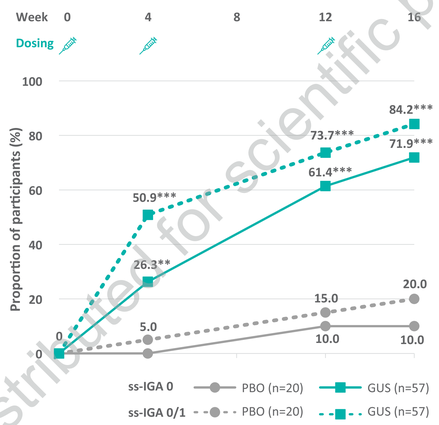
Baseline body disease severity of those patients with ss-IGA ≥2 at baseline (total, n=77)



BSA=body surface area; IGA=Investigator's Global Assessment; NRS=numeric rating scale; PASI=Psoriasis Area and Severity Index; PsO=psoriasis; PSSI=Psoriasis Scalp Severity Index; SSA=Scalp Surface Area of disease; ss-IGA=scalp-specific Investigator's Global Assessment.

Greater proportions of participants in the GUS group achieved ss-IGA 0 and ss-IGA 0/1 vs PBO through Week 16

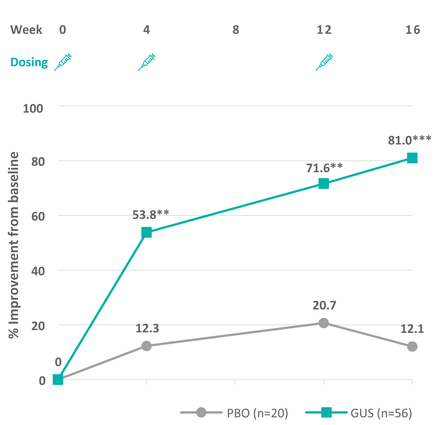
Proportions of participants with ss-IGA 0 and ss-IGA 0/1 through Week 16†



*P-values are based on Cochran-Mantel-Haenszel test stratified by Fitzpatrick Skin Type (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. †Among participants with at least mild scalp PsO (ss-IGA ≥2). **Nominal p<0.01 vs PBO. ***Nominal p<0.001 vs PBO. GUS=guselkumab; PBO=placebo; PsO=psoriasis; ss-IGA=scalp-specific Investigator's Global Assessment.*

Greater mean percent improvement from baseline PSSI was observed in the GUS group vs the PBO group through Week 16

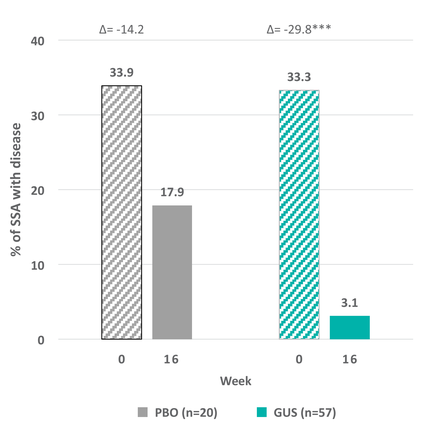
Percent improvement from baseline (LS mean) PSSI through Week 16†



*LS means and p-values were based on MMRM. Zero change was assigned after participants discontinued study agent due to lack of efficacy/worsening of PsO or initiated a prohibited PsO treatment. Missing data were handled by MMRM under missing at random assumption. †Among participants with at least mild scalp PsO (ss-IGA ≥2). **Nominal p<0.01 vs PBO. ***Nominal p<0.001 vs PBO. GUS=guselkumab; LS=Least squares; MMRM=Mixed-Effect Model Repeated Measures; PBO=placebo; PSSI=Psoriasis Scalp Severity Index; PsO=psoriasis; ss-IGA=scalp-specific Investigator's Global Assessment.*

Greater mean change from baseline SSA was observed in the GUS group vs the PBO group at Week 16

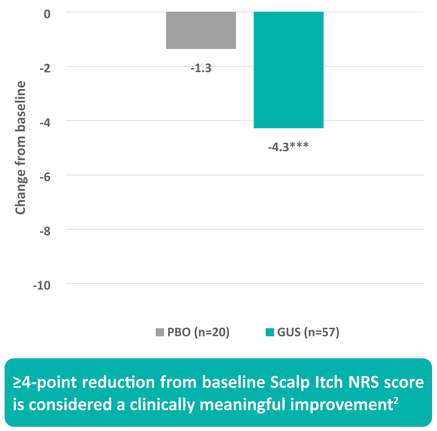
Mean SSA at baseline and Week 16†
Δ = LS mean change at Week 16



*LS means and p-values were based on MMRM. Zero change was assigned after participants discontinued study agent due to lack of efficacy/worsening of PsO or initiated a prohibited PsO treatment. Missing data were handled by MMRM. †Among participants with at least mild scalp PsO (ss-IGA ≥2). ***Nominal p<0.001 vs PBO. GUS=guselkumab; LS=least squares; MMRM=Mixed-Effect Model Repeated Measures; PBO=placebo; PsO=psoriasis; SSA=Scalp Surface Area of disease; ss-IGA=scalp-specific Investigator's Global Assessment.*

Greater mean reduction in Scalp Itch NRS was observed in the GUS group vs the PBO group at Week 16

Change from baseline (LS mean) in Scalp Itch NRS score at Week 16†



≥4-point reduction from baseline Scalp Itch NRS score is considered a clinically meaningful improvement[2]

*LS means and p-values were based on ANCOVA. Zero change was assigned after participants discontinued study agent due to lack of efficacy/worsening of PsO or initiated a prohibited PsO treatment. Missing data were not explicitly imputed. †Among participants with at least mild scalp PsO (ss-IGA ≥2). ***Nominal p<0.001 vs PBO. ANCOVA=analysis of covariance; GUS=guselkumab; LS=least squares; NRS=numeric rating scale; PBO=placebo; PsO=psoriasis; ss-IGA=scalp-specific Investigator's Global Assessment.*

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References

1. Fitzpatrick TB, et al. *Arch Dermatol.* 1988;124(6):869-871.
2. Wang Y, et al. *J Dermatolog Treat*. 2019;30:775-783.

Disclosures

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