VISIBLE COHORT B: SCALP CLEARANCE THROUGH WEEK 48 WITH GUSELKUMAB 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 comprises of cohorts:

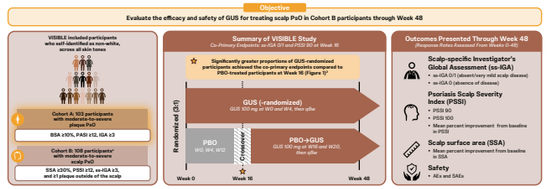
Cohort A: participants with moderate-to-severe plaque PsO

Cohort B: participants with moderate-to-severe scalp PsO

A dedicated scalp cohort was included as scalp is the most commonly involved special site among individuals with moderate-to-severe plaque PsO

- **Scalp PsO can negatively impact daily life, with symptoms and signs including pruritus, intense scaling, and even alopecia, causing great physical and social distress[1]**
- **Treatment of scalp PsO in skin of color patients requires comprehensive consideration of haircare practices, including hair texture, styling, and washing schedule[2]**

METHODS



*Efficacy was assessed in all participants who met Cohort B inclusion criteria (N=102). AE=Adverse event; BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; q8w=Every 8 weeks; SAE=Serious adverse event; SSA=Scalp surface area; ss-IGA=Scalp-specific Investigator's Global Assessment.

CONCLUSIONS

Through Week 48, VISIBLE Cohort B study results showed:

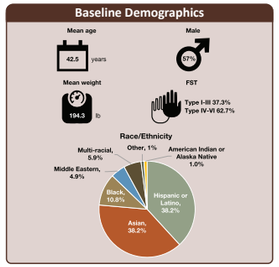
- **>80%** of GUS-randomized participants achieved absent/very mild scalp disease
- **ss-IGA 0 PSSI 100** >65% of GUS-randomized participants achieved complete scalp clearance
- **~95%** mean % improvement from baseline in SSA and PSSI among GUS-randomized participants
- No new safety signals were identified

These results demonstrate that GUS is a highly effective and durable treatment for moderate-to-severe scalp PsO in participants across all skin tones

RESULTS

BASELINE CHARACTERISTICS (N=102)

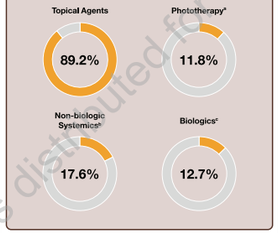
Baseline Demographics



Baseline 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)

Previous PsO Medications/Therapies

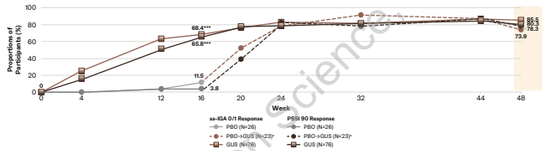


*Includes PUVA or UVB. †Includes PUVA, methotrexate, cyclosporine, acitretin. ‡Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab. FST=Fitzpatrick Skin Type; GUS=Guselkumab; PBO=Placebo; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; PUVA=Psoralen plus ultraviolet A; SSA=Scalp surface area; ss-IGA=Scalp-specific Investigator's Global Assessment; UVB=Ultraviolet B.

Among GUS-randomized participants, the significantly greater ss-IGA 0/1 and PSSI 90 response rates vs PBO at Week 16 improved through Week 48

- Response rates were similar for GUS-randomized and PBO→GUS participants at Week 48

Figure 1. Proportions of Participants Achieving ss-IGA 0/1 and PSSI 90 Through Week 48



***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel (CMH) test stratified by FST (I-II/III-VI). *For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included in Weeks 20-48. 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. GUS=Guselkumab; PBO=Placebo; PSSI=Psoriasis Scalp Severity Index; PsO=Psoriasis; ss-IGA=Scalp-specific Investigator's Global Assessment.

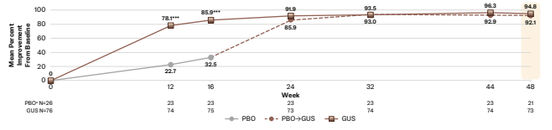
Figure 2. Participant Who Achieved ss-IGA 0/1 at Week 16 and Complete Scalp Clearance (ss-IGA 0 and PSSI 100) at Week 48

PSSI=Psoriasis Scalp Severity Index; SSA=Scalp surface area; ss-IGA=Scalp-specific Investigator's Global Assessment.

Mean percent improvement in SSA and PSSI for the GUS group was >85% at Week 16 and improved to ~95% at Week 48 (Figures 3 and 4)

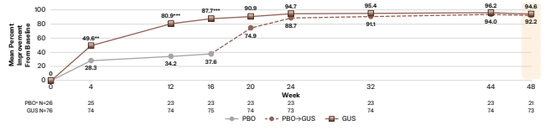
- PBO→GUS participants achieved response rates similar to those of the GUS-randomized participants at Week 48

Figure 3. Mean Percent Improvement From Baseline in SSA Through Week 48



***p<0.001 vs PBO; p-values were based on the MMRM. *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 discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, zero change from baseline was assigned from that point onward. Missing data were not imputed. FST=Fitzpatrick Skin Type; GUS=Guselkumab; MMRM=Mixed-effect repeated measures; PBO=Placebo; PsO=Psoriasis; SSA=Scalp surface area

Figure 4. Mean Percent Improvement From Baseline in PSSI Through Week 48

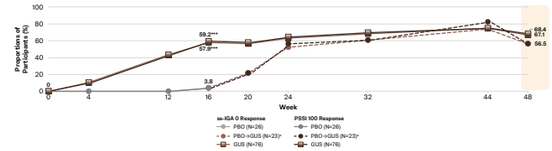


**p<0.01 vs PBO; ***p<0.001 vs PBO; p-values were based on the MMRM. *For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. When participants discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, zero change from baseline was assigned from that point onward. Missing data were not imputed. GUS=Guselkumab; PBO=Placebo; PsO=Psoriasis; MMRM=Mixed-effect model repeated measures.

Significantly greater proportions of GUS-randomized participants (>57%) achieved scalp clearance (ss-IGA 0 and PSSI 100) compared to PBO-treated participants at Week 16, with response rates generally improving through Week 48

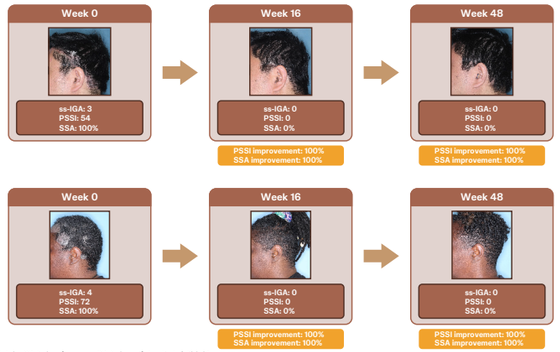
- By Week 48, response rates were similar for GUS-randomized and PBO→GUS participants

Figure 5. Proportions of Participants Achieving ss-IGA 0 and PSSI 100 Through Week 48



***p<0.001 vs PBO; p-values were based on the CMH test stratified by FST (I-II/III-VI). *For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included in Weeks 20-48. 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. CMH=Cochran-Mantel-Haenszel; GUS=Guselkumab; FST=Fitzpatrick Skin Type; PBO=Placebo; PSSI=Psoriasis Scalp Severity Index; PsO=Psoriasis; ss-IGA=Scalp-specific Investigator's Global Assessment.

Figure 6. Participants Who Achieved Complete Scalp Clearance (ss-IGA 0 and PSSI 100) at Week 16 and Week 48



PSSI=Psoriasis Scalp Severity Index; SSA=Scalp surface area; ss-IGA=Scalp-specific Investigator's Global Assessment.

Safety findings were consistent with the established GUS safety profile, with no new safety signals identified through Week 48

Table 1. Key Safety Information Through Week 48

	PBO→GUS[a] Week 16-48	GUS Week 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%)[b]
Participants with ≥1 injection site reaction	0	1 (1.2%)
Infections	4 (16.7%)	27 (33.3%)
Serious infections	0	0

Through Week 48 There Were No Cases of: Death; Malignancy; Active TB; MACE; IBD; Serum-like sickness or anaphylaxis

[a]Includes only PBO participants who crossed over to receive GUS. [b]SAEs in GUS-treated participants were 1 event each of angina pectoris and pancreatitis. Data shown are n (%), unless otherwise indicated. 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; GUS=Guselkumab; IBD=Inflammatory bowel disease; MACE=Major adverse cardiovascular events; MedDRA=Medical Dictionary for Regulatory Activities; PBO=Placebo; SAE=Serious adverse event; TB=Tuberculosis.

References

1. Crowley J. *J Drugs Dermatol.* 2010;9:912-8.
2. Alexis AF and Blackcloud P. *J Clin Aesthet Dermatol.* 2014;7:16-24.
3. Alexis A, et al. Poster presented at: Maui Derm Hawaii; January 22-26, 2024.

Disclosures

AM: has received grants (funds to institution) and/or served as consultant/advisor for AbbVie, Almirall, Arcutis, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, Johnson & Johnson, L'Oréal, Nutrafol, Pfizer, Revian, Sanofi-Genzyme, and UCB. **TB:** is currently a principal investigator for studies being sponsored by AbbVie, Castle, CorEvitas, Dermavant, Galderma, Mindera, and Pfizer; has additional research funding from Novartis and Regeneron; has served as an advisor for AbbVie, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Sun Pharma, and UCB. **SS:** received honoraria or research grants from AbbVie, Aclaris, Almirall, Alumis, Amgen, Arcutis, Caliway, Candesant, Eli Lilly, Endo Pharmaceuticals, Galderma, Janssen, Moberg, Nielsen, Pfizer, Sun Pharma, and Teoxane. **TA, OC, DC, TM:** are employees of Janssen, a Johnson & Johnson company; employees may own stock/stock options in Johnson & Johnson. **RR:** is a principal investigator for AbbVie, Amgen, Eli Lilly, Incyte, Jasper Pharmaceutical, Johnson & Johnson, Pfizer, and Sanofi. **JY:** has served as a speaker/ consultant/ honoraria/ trialist for AbbVie, Amgen, Anacor, Arcutis, Astellas, Bausch, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Eli Lilly, Forward, Galderma, Janssen, LEO Pharma, Medimmune, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Sun Pharma, Takeda, UCB, and Xenon. **GH:** is a consultant, speaker, or received research support from AbbVie, Amgen, Athenex, Beiersdorf, Boehringer Ingelheim, Bond Avillion, Bristol Myers Squibb, Castle Biosciences, Celgene, CeraVe, Dermavant, Dermtech, Janssen, LEO Pharma, Eli Lilly, MC2, MedX, Novartis, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, Sun Pharma, Takeda, and UCB. **SCT:** has received honoraria/stock options serving as an advisor/consultant and/or speaker for AbbVie, Arcutis, Armis, Avita, Beiersdorf, Biorez, Bristol Myers Squibb, Cara, Dior, Eli Lilly, EPI, Evolus, Galderma, GloGetter, Hugel America, Janssen, Johnson & Johnson, L'Oréal, Medscape/WebMD, MJH LifeSciences, Piction Health, Sanofi-Regeneron, Scientis US, UCB, and Vichy; has received honoraria/Board of Directors from Mercer Strategies; served as an author/received royalties from McGraw-Hill; served on the editorial board for *Archives in Dermatologic Research, British Journal of Dermatology* (peer reviewer), *Cutis,* and *Practical Dermatology;* served as an investigator for Concert Pharmaceuticals, Croma-Pharma, Eli Lilly, and Pfizer.

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