VISIBLE COHORT B: GUSELKUMAB SCALP CLEARANCE RESULTS THROUGH WEEK 100 IN PARTICIPANTS WITH MODERATE-TO-SEVERE SCALP PSORIASIS ACROSS ALL SKIN TONES

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BACKGROUND

VISIBLE is a Phase 3b, multicenter, randomized, double-blinded, placebo (PBO)-controlled study of guselkumab (GUS) focused on individuals with skin of color (SoC) across all skin tones

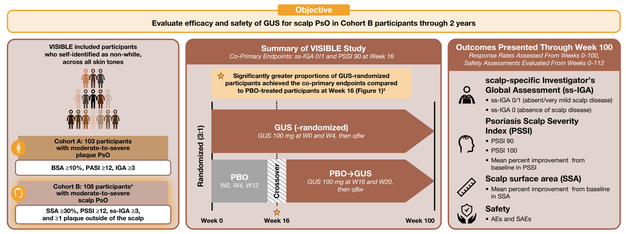
VISIBLE is comprised of 2 cohorts:

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

A dedicated scalp PsO cohort was included due to the condition's high prevalence, especially in individuals with SoC

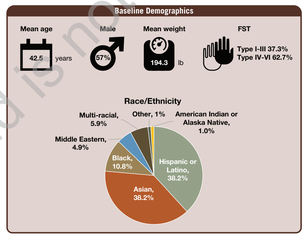
- Scalp PsO can negatively impact daily life, with symptoms and signs including pruritus, intense scaling, and even alopecia, causing great physical and social distress[1]
- Treatment in SoC populations can present additional challenges due to hair texture, styling, washing routines, and cultural hair care practices[2]

OBJECTIVE/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, **q8w**=every 8 weeks, **SAE**=serious adverse event, **W**=week.*

BASELINE CHARACTERISTICS (N=102)



Baseline Disease Characteristics

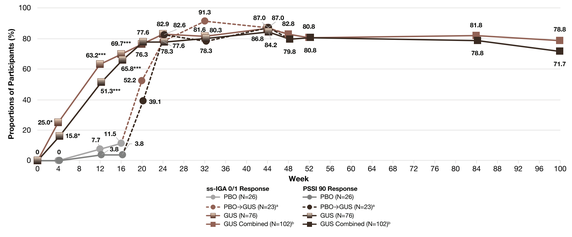
	PBO (N=26)	GUS (N=76)
PsO Duration, y	11.3 (12.8)	11.3 (9.8)
IGA, n (%)		
Moderate [3]	20 (76.9)	64 (84.2)
Severe [4]	6 (23.1)	12 (15.8)
PASI (0–72)	34.0 (11.8)	34.4 (13.7)
BSA, %	56.6 (22.4)	60.8 (27.1)

*[a]Includes PUVA or UVB. [b]Includes PUVA, methotrexate, cyclosporine, acitretin. [c]Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab. **BSA**=body surface area, **FST**=Fitzpatrick Skin Type, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **PUVA**=psoralen plus ultraviolet A, **UVB**=ultraviolet B.*

RESULTS

Among GUS-randomized participants, the significantly greater ss-IGA O/1 and PSSI 90 response rates vs PBO at Week 16 improved to >70% for both the GUS and PBO→GUS groups through Week 100

Figure 1. Proportions of Participants Achieving ss-IGA O/1 and PSSI 90 Through Week 100 (NRI)



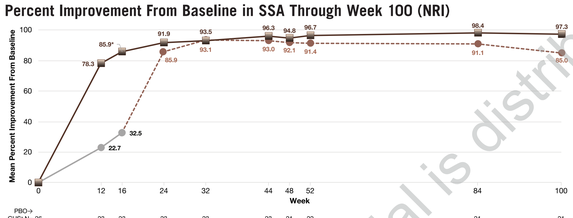
p<0.05 vs PBO; ***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel (CMH) test stratified by Fitzpatrick Skin Type (Type I-III/Type IV-VI). †For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included in Weeks 20–48. ‡Includes participants randomized to GUS at baseline and participants randomized to PBO at baseline who then crossed over to receive GUS at or after Week 16. 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, **NRI**=non-responder imputation, **PBO**=placebo, **PsO**=psoriasis, **PSSI**=Psoriasis Scalp Severity Index, **ss-IGA**=scalp-specific Investigator's Global Assessment.*

Figure 2. Scalp Clearance Journey for a Participant With Moderate-to-Severe Disease (ss-IGA=3; PSSI=35; SSA=70%) at Baseline

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

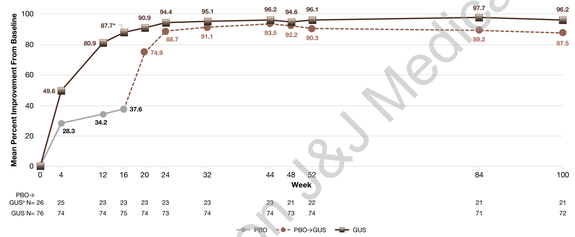
Mean percent improvement in SSA and PSSI at Week 16 for the GUS group was >85%, and improved to ~90% for both the GUS and PBO→GUS groups through Week 100 (Figures 3 and 4)

Figure 3. Mean Percent Improvement From Baseline in SSA Through Week 100 (NRI)



p<0.001 vs PBO; p-values are based on the mixed model for repeated measures; explanatory variables included treatment group, visit, baseline score, by FST (I-III/IV-VI), an interaction term of visit with treatment group, and an interaction term of visit with baseline score. †For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included. Zero change from baseline was assigned if participants discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment (intercurrent events). **FST=Fitzpatrick Skin Type, **GUS**=guselkumab, **NRI**=non-responder imputation, **PBO**=placebo, **PsO**=psoriasis, **PSSI**=Psoriasis Scalp Severity Index, **SSA**=scalp surface area.*

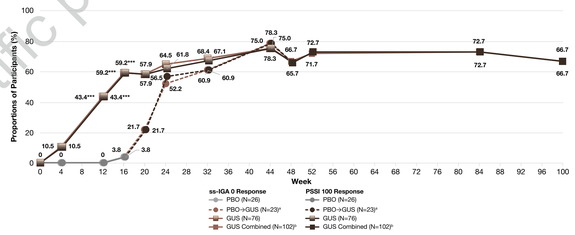
Figure 4. Mean Percent Improvement From Baseline in PSSI Through Week 100 (NRI)



p<0.001 vs PBO; p-values are based on the mixed model for repeated measures; explanatory variables included treatment group, visit, baseline score, FST (Type I-III/Type IV-VI), an interaction term of visit with treatment group, and an interaction term of visit with baseline score. †For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included. Zero change from baseline was assigned if participants discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment (intercurrent events). **FST=Fitzpatrick Skin Type, **GUS**=guselkumab, **NRI**=non-responder imputation, **PBO**=placebo, **PsO**=psoriasis, **PSSI**=Psoriasis Scalp Severity Index.*

Significantly greater proportions of GUS-randomized participants (>59%) achieved scalp clearance (ss-IGA O and PSSI 100) compared to PBO-treated participants at Week 16, with response rates generally improving to >66% for both the GUS and PBO→GUS groups through Week 100

Figure 5. Proportions of Participants Achieving ss-IGA O and PSSI 100 Through Week 100 (NRI)



p<0.05 vs PBO; ***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel (CMH) test stratified by FST (I-III/IV-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. ‡Includes participants randomized to GUS at baseline and participants randomized to PBO at baseline who then crossed over to receive GUS at or after Week 16. 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. **FST=Fitzpatrick Skin Type, **GUS**=guselkumab, **NRI**=non-responder imputation, **PBO**=placebo, **PsO**=psoriasis, **PSSI**=Psoriasis Scalp Severity Index, **ss-IGA**=scalp-specific Investigator's Global Assessment.*

Figure 6. Scalp Clearance Journey for a Participant With Moderate-to-Severe Disease (ss-IGA=3; PSSI=32; SSA=40%) at Baseline

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 112**
- **Through Week 112, there were no events of death, cancer, active tuberculosis, major adverse cardiovascular events (MACE), inflammatory bowel disease, or serum-like sickness/anaphylaxis**

Table 1. Key Safety Information and AEs of Interest Through Week 112

	PBO (Weeks 0–16) N=27	GUS (Weeks 0–16) N=81	PBO→GUS[a] (Weeks 16–112) N=24	GUS (Weeks 0–112) N=81
Total participant-years of follow-up	8.0	25.1	40.9	168.1
Median participant-years of follow-up	0.3	0.3	1.8	2.1
Participants with ≥1 AE	62.6 (20.3, 146.2)	143.4 (100.5, 198.6)	105.2 (76.2, 141.8)	129.7 (113.0, 148.1)
AEs leading to discontinuation of study agent	0 (0, 37.5)	0 (0, 11.9)	0 (1, 7.3)	0 (0, 1.8)
Serious AEs[b]	12.5 (0.3, 69.8)	0 (0, 11.9)	0 (0, 7.3)	1.8 (0.4, 5.2)
AEs of interest				
Infections[c]	0 (0, 37.5)	0 (0, 11.9)	36.7 (20.6, 60.6)	45.2 (35.6, 56.6)
Serious infections	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0.59 (0.0, 3.3)
Clinically important hepatic disorder[d]	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
MACE[e]	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
Malignancy	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
Venous thromboembolism	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
Serum-like sickness anaphylaxis	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
Tuberculosis	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)
Inflammatory bowel disease[f]	0 (0, 37.5)	0 (0, 11.9)	0 (0, 7.3)	0 (0, 1.8)

*Data shown are number of events per 100 participant-years (95% CI). [a]Includes only PBO participants who crossed over to receive GUS. [b]Weeks 0–16: 1 PBO participant had a viral rash; Weeks 0–112: 1 GUS participant had angina pectoris, 1 GUS participant had pancreatitis, and 1 GUS participant had right lower lobe pneumonia. [c]The most common infections for all GUS-treated participants (≥5%) included upper respiratory tract infections (24.7%), COVID-19 (16.0%), and nasopharyngitis (7.4%). [d]No clinically important hepatic disorder adverse events were based on a narrow Hepatic Disorders Standardised MedDRA Queries (SMQ) search and recorded on the case report form as serious or leading to study treatment discontinuation. [e]MACE includes sudden cardiac death, nonfatal myocardial infarction, and nonfatal stroke. [f]IBD includes preferred terms of Crohn's disease, ulcerative colitis, and IBD. 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 27.1. **AE**=adverse event, **CI**=confidence interval, **COVID-19**=coronavirus disease 2019, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **MACE**=major adverse cardiovascular events, **MedDRA**=Medical Dictionary for Regulatory Activities, **PBO**=placebo.*

CONCLUSIONS

Through Year 2, VISIBLE Cohort B study results showed:

- **>70%** of all GUS-treated participants achieved absent/very mild scalp disease (ss-IGA0/1 and PSSI 90)
- **~90%** mean % improvement from baseline in SSA and PSSI among all GUS-treated participants
- **>66%** of all GUS-treated participants achieved complete scalp clearance (ss-IGA 0 PSSI 100)
- No new safety signals were identified

Scalp clearance responses achieved at Week 16 were maintained or improved with continuous GUS treatment through Week 100 demonstrating high efficacy and durable responses for moderate-to-severe scalp PsO in participants across all skin tones

PRESENTED AT: Society of Dermatology Physician Associates (SDPA) Annual Fall Conference 2025; San Antonio, TX, USA; November, 5–9, 2025. **Reference: 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.** McMichael A, et al. *JAMA Dermatol.* 2025:e251849. doi: 10.1001/jamadermatol.2025.1849. Epub ahead of print. **Acknowledgements:** Medical writing support was provided by Teresa Tartaglione, PharmD, of Certara, Radnor, PA under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298-304). This poster was supported by Johnson & Johnson, Horsham, PA, USA. Layout design and reformatting for this encore presentation were provided by Samita Warang of SIRO Medical Writing Pvt. Ltd., Thane, Maharashtra, India (sponsored by Johnson & Johnson). **Disclosures: A McMichael** has received grants (funds to institution) and/or served as consultant/advisor for AbbVie, Almirall, Arcutis, Bristol Myers Squibb, Eli Lilly, Galderma, Johnson & Johnson, Kenwue, LOréal, Nutrafol, Pfizer, Revian, Sanofi-Genzyme, and UCB. **T Bhutani** 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; and has served as an advisor for AbbVie, Arcutis, Boehringer-Ingelheim, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, LEO, Pfizer, Novartis, Sun, and UCB. **C Kindred** has served as a consultant, advisory board member, and/or speaker for AbbVie, Eli Lilly, Johnson & Johnson, Novartis, Pfizer, Regeneron, Sanofi, Sun, and UCB; has served as an investigator and/or medical board member for AbbVie, Aerolase, Eli Lilly, Pfizer, and Selphyl; and is a journal editor for Cutis. **S Smith** receives honoraria or research grants from AbbVie, Aclaris, Almirall, Alumis, Amgen, Arcutis, Caliway, Candesant, Eli Lilly, Endo Pharmaceuticals, Galderma, Johnson & Johnson, Moberg, Nielsen, Pfizer, Sun, and Texoane. **O Choi** was an employee of Johnson & Johnson at the time this work was conducted and is a shareholder of Johnson & Johnson; she is currently an employee of Apogee Therapeutics. **T Alkousakis**, **D Chan, T Ma** and **K Rowland** are employees of Johnson & Johnson; employees may own stock/stock options in Johnson & Johnson. **R Radusky** is a principal investigator for AbbVie, Amgen, Eli Lilly, Incyte, Jasper Pharmaceutical, Johnson & Johnson, Pfizer, and Sanofi. **J Yeung** has served as a speaker/consultant/honoraria/trialist for AbbVie, Amgen, Anacor, Arcutis, Astella, Bausch, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Eli Lilly, Forward, Galderma, Johnson & Johnson, LEO, Medimmune, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Sun, Takeda, UCB, and Xenon. **G Han** is a consultant, speaker, or received research support from AbbVie, Amgen, Athenex, Beiersdorf, Bristol Myers Squibb, Boehringer Ingelheim, Bond Avillion, Castle Biosciences, Celgene, CeraVe, Dermavant, Dermtech, Eli Lilly, Johnson & Johnson, LEO, MC2, MedX, Novartis, Ortho Dermatologics, Pfizer, Regeneron/Sanofi, Sun, Takeda, and UCB. **SC Taylor** 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, 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; and served as an investigator for Concert Pharmaceuticals, Croma-Pharma, Eli Lilly, and Pfizer.
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