VISIBLE COHORT A: SKIN CLEARANCE THROUGH WEEK 48 WITH GUSELKUMAB IN PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS ACROSS ALL SKIN TONES

A. Alexis,[1] A.O. Rodriguez,[2] G. Yadav,[3,4] S.K. Tyring,[5] O. Choi,[6] T. Alkousakis,[6] D. Chan,[6] T. Ma,[7] M. Sauder,[3,8] J. Alonso-Llamazares,[9] S.R. Desai[10,11]

[1]Weill Cornell Medicine, New York, NY, USA; [2]Nashville Skin Comprehensive Dermatology Center, Nashville, TN, USA; [3]University of Toronto, Toronto, ON, Canada; [4]FACET Dermatology, Toronto, ON, Canada; [5]Center for Clinical Studies, Webster, TX, USA; [6]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [7]Janssen Research & Development, LLC, Spring House, PA, USA; [8]Probity Medical Research, Waterloo, ON, Canada; [9]Driven Research LLC, Coral Gables, FL, USA; [10]Innovative Dermatology, Plano, TX, USA; [11]University of Texas Southwestern Medical Center, Dallas, TX, USA

BACKGROUND/OBJECTIVE

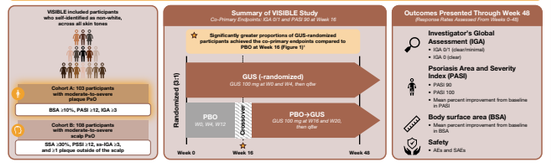
VISIBLE is an ongoing Phase 3b, multicenter, randomized, double-blinded, placebo (PBO)-controlled study of guselkumab (GUS) for the treatment of participants with moderate-to-severe plaque psoriasis (PsO) across all skin tones

VISIBLE comprises 2 cohorts:

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

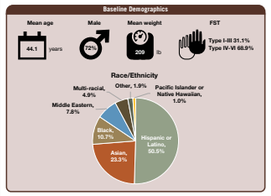
VISIBLE was intentionally designed to address historical disparities in clinical trials and enable healthcare professionals to make evidence-based medical decisions for people of all skin tones

METHODS



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; sc-IGA=Scalp-specific IGA; SSA=Scalp surface area; W=Week.

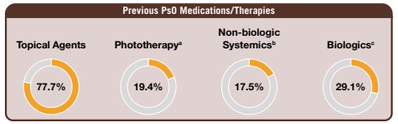
BASELINE CHARACTERISTICS (N=103)



Baseline Disease Characteristics

	PBO (N=26)	GUS (N=77)
PsO Duration, y	14.9 (8.8)	14.9 (11.0)
IGA, n (%)		
Moderate	21 (80.8%)	57 (74.0%)
Severe	5 (19.2%)	20 (26.0%)
PASI (0-72)	19.8 (6.2)	21.2 (9.9)
BSA, %	26.1 (15.9%)	27.0 (20.4%)

Previous PsO Medications/Therapies



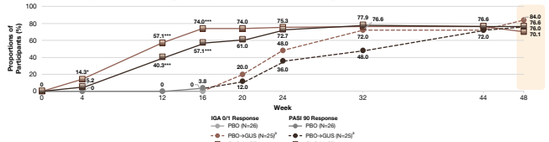
BSA=body surface area; FST=Fitzpatrick Skin Type; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis; PUVA=Psoralen plus ultraviolet A; UVB=Ultraviolet B. [a]Includes PUVA or UVB. [b]Includes acitretin, cyclosporine, methotrexate, and oral LEO Pharma; has served on an advisory board or consulted for AbbVie, Allergan, Almirall, Alphyn, Amgen, Apogee, Arcutis, Avita Medical, Bausch Health, Beiersdorf, Bristol Myers Squibb, Canfield, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Genentech, Genzyme, Incyte, Janssen, LEO Pharma, L'Oréal, Ortho, Pfizer, Sanofi-Regeneron, Swiss American, UCB, and VisualDx; has served as a speaker for Bristol Myers Squibb, Janssen, Johnson & Johnson, L'Oréal, Regeneron, and Sanofi-Genzyme; has received royalties from Elsevier, Springer, Wiley-Blackwell, and Wolters Kluwer Health; and has received equipment from Aerolase. **AOR** has served as an advisor and/or speaker for Arcutis, Dermavent, Eli Lilly, EPI Health, Janssen, LEO Pharma, Novartis, Sciton, Sun Pharma, and UCB; owns stock in Strathspey Crown. **GY:** is currently a principal investigator for studies being sponsored by AbbVie, Amgen, Aralez, Janssen, Eli Lilly and Sanofi; has served as an advisor for AbbVie, Amgen, Aralez, Arcutis, Bausch Health, Biodermа, Bristol Myers Squibb, Byrdie, Galderma, Incyte, Janssen, Johnson & Johnson, LEO Pharma, L'Oréal, Medexus, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, UCB, and Unilever. **SKT:** has received grants, consultant/speaker honoraria (paid to institution) from AbbVie, Agenus, AiCuris GmbH, Almirall, Amgen, Bayer, Bristol Myers Squibb, Demira, Dr Reddy's Laboratory, Eli Lilly, Foamix Pharma, Galderma, Genocea Biosciences, GlaxoSmithKline Immunology, Glenmark Pharma, IQVIA, Janssen Research & Development, Kiniksa Pharma, LEO Laboratories, Menlo Therapeutics, Merck, Novartis, Nycomed Amersham, Parexel, Quintiles Pharma, Regeneron Pharma, Sanofi, Trevi Therapeutics, UCB, and Vical. **OC, TA, DC,** and **TM:** are employees of Janssen, a Johnson & Johnson company; employees may own stock/stock options in Johnson & Johnson. **MS:** has served as an investigator and/or advisor and/or speaker for AbbVie, Alumis, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Novartis, Sun Pharma, Takeda, and UCB. **JA-L:** has served as a speaker for Arcutis, Eli Lilly, Incyte, and UCB; as an advisor for Arcutis and LEO Pharma; and as an investigator for Amgen, Eli Lilly, Janssen, and Takeda. **SRD:** serves as a consultant and/or investigator for a variety of different organizations including Eli Lilly, Galderma, Incyte, Janssen, L'Oréal, Pfizer and others; serves in numerous leadership capacities within Dermatology.[c]Includes adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab.

RESULTS

Significantly greater IGA 0/1 and PASI 90 response rates were achieved by GUS-randomized vs PBO-treated participants at Week 16, and response rates were sustained or improved through Week 48

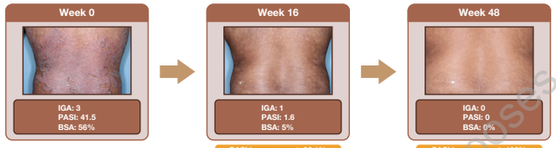
- By Week 48, response rates were similar for GUS-randomized and PBO→GUS participants

Figure 1. Proportions of Participants Achieving IGA 0/1 and PASI 90 Through Week 48



FST=Fitzpatrick Skin Type; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis. *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 vs 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. 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.

Figure 2. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16 and Complete Skin Clearance (IGA 0 and PASI 100) at Week 48

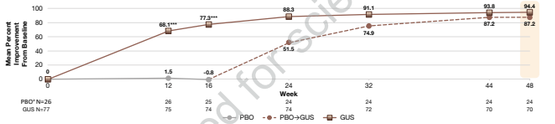


BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index.

The GUS-randomized group achieved >94% mean improvement in BSA and PASI through Week 48 (Figures 3 and 4)

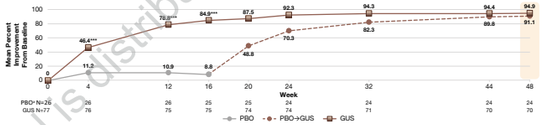
- Mean percent improvement in BSA and PASI continuously increased from Week 16 through Week 48

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



GUS=Guselkumab; MMRM=Mixed model for repeated measures; PBO=Placebo; PsO=Psoriasis.***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.

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

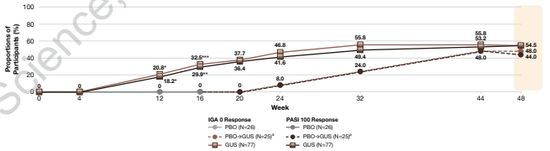


GUS=Guselkumab; MMRM=Mixed model for repeated measures; PBO=Placebo; PsO=Psoriasis.***p<0.001 vs PBO; p-values were based on the MMRM. *For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. When participants discontinued study agent 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.

Significantly greater proportions of GUS-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) compared to PBO at Week 16, with response rates continuing to improve through Week 48

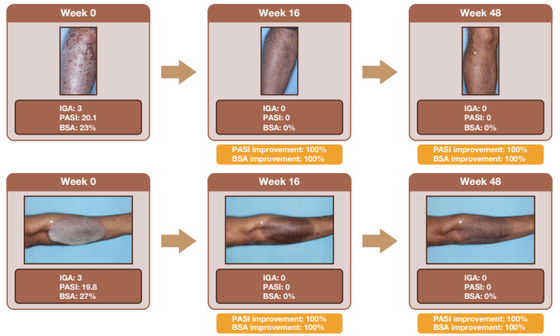
- By Week 48, response rates were similar for GUS-randomized and PBO→GUS participants

Figure 5. Proportions of Participants Achieving IGA 0 and PASI 100 Through Week 48



CMH=Cochran-Mantel-Haenszel; FST=Fitzpatrick Skin Type; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis.*p<0.05 vs PBO; **p<0.01 vs PBO; ***p<0.001 vs PBO; p-values were based on the CMH test stratified by FST (I-III vs 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. 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.

Figure 6. Participants Who Achieved Complete Skin Clearance (IGA 0 and PASI 100) at Week 16 and Week 48



BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index.

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* Week 16-48	GUS Week 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%)[a]
Participants with ≥1 SAE	1 (4.0%)[b]	1 (1.3%)[c]
Participants with ≥1 injection site reaction	0	0
Infections	5 (20.0%)	28 (36.4%)
Serious infections	1 (4.0%)[b]	1 (1.3%)[c]

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

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; PBO=Placebo; TB=tuberculosis. *Includes only PBO participants who crossed over to receive GUS. [a]AEs leading to discontinuation among GUS-treated participants were 1 event each of pregnancy and impetiginized atopic dermatitis. [b]SAE in PBO-treated participant was 1 event of cellulitis. [c]SAE in GUS-treated participant was 1 event of pyelonephritis.

CONCLUSIONS

Through Week 48, VISIBLE Cohort A study results showed:

- **>70%** of GUS-randomized participants achieved clear/almost clear skin (IGA 0/1 and PASI 90)
- **≥94%** mean % improvement from baseline in BSA and PASI among GUS-randomized participants
- IGA 0 PASI 100 **>50%** of GUS-randomized participants achieved complete clearance
- No new safety signals were identied
- Clinical responses achieved at Week 16 were maintained or improved through Week 48 with continuous GUS treatment, demonstrating high efficacy and durable responses in participants across all skin tones

References

1. Alexis A, et al. Poster presented at: Fall Clinical Dermatology Conference; October 19-22, 2023.

Disclosures

AA: has received grants (funds to institution) from AbbVie, Amgen, Arcutis, Castle, Dermavent, Galderma, Incyte, and LEO Pharma; has served on an advisory board or consulted for AbbVie, Allergan, Almirall, Alphyn, Amgen, Apogee, Arcutis, Avita Medical, Bausch Health, Beiersdorf, Bristol Myers Squibb, Canfield, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Genentech, Genzyme, Incyte, Janssen, LEO Pharma, L'Oréal, Ortho, Pfizer, Sanofi-Regeneron, Swiss American, UCB, and VisualDx; has served as a speaker for Bristol Myers Squibb, Janssen, Johnson & Johnson, L'Oréal, Regeneron, and Sanofi-Genzyme; has received royalties from Elsevier, Springer, Wiley-Blackwell, and Wolters Kluwer Health; and has received equipment from Aerolase. **AOR** has served as an advisor and/or speaker for Arcutis, Dermavent, Eli Lilly, EPI Health, Janssen, LEO Pharma, Novartis, Sciton, Sun Pharma, and UCB; owns stock in Strathspey Crown. **GY:** is currently a principal investigator for studies being sponsored by AbbVie, Amgen, Aralez, Janssen, Eli Lilly and Sanofi; has served as an advisor for AbbVie, Amgen, Aralez, Arcutis, Bausch Health, Biodermа, Bristol Myers Squibb, Byrdie, Galderma, Incyte, Janssen, Johnson & Johnson, LEO Pharma, L'Oréal, Medexus, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, UCB, and Unilever. **SKT:** has received grants, consultant/speaker honoraria (paid to institution) from AbbVie, Agenus, AiCuris GmbH, Almirall, Amgen, Bayer, Bristol Myers Squibb, Demira, Dr Reddy's Laboratory, Eli Lilly, Foamix Pharma, Galderma, Genocea Biosciences, GlaxoSmithKline Immunology, Glenmark Pharma, IQVIA, Janssen Research & Development, Kiniksa Pharma, LEO Laboratories, Menlo Therapeutics, Merck, Novartis, Nycomed Amersham, Parexel, Quintiles Pharma, Regeneron Pharma, Sanofi, Trevi Therapeutics, UCB, and Vical. **OC, TA, DC,** and **TM:** are employees of Janssen, a Johnson & Johnson company; employees may own stock/stock options in Johnson & Johnson. **MS:** has served as an investigator and/or advisor and/or speaker for AbbVie, Alumis, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Novartis, Sun Pharma, Takeda, and UCB. **JA-L:** has served as a speaker for Arcutis, Eli Lilly, Incyte, and UCB; as an advisor for Arcutis and LEO Pharma; and as an investigator for Amgen, Eli Lilly, Janssen, and Takeda. **SRD:** serves as a consultant and/or investigator for a variety of different organizations including Eli Lilly, Galderma, Incyte, Janssen, L'Oréal, Pfizer and others; serves in numerous leadership capacities within Dermatology.

This study was supported by Janssen Scientific Affairs, LLC • Previously presented at SOCU 2024; September 13-15, 2024; New York, NY, USA.

Presented at Fall Clinical Dermatology Conference (FCDC) 2024; October 24-27, 2024; Wynn Las Vegas, NV, USA.