VISIBLE: CLEARANCE AND SYMPTOM IMPROVEMENT WITH GUSELKUMAB AT WEEK 16 IN SKIN OF COLOR PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

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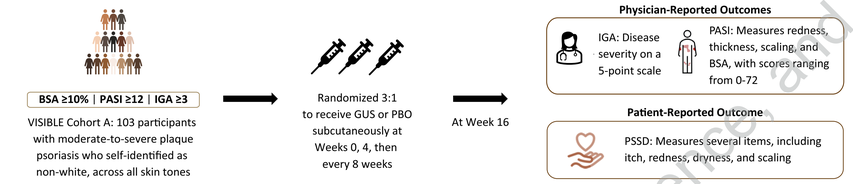
BACKGROUND/OBJECTIVE

- 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 psoriasis (PsO) across all skin tones
- VISIBLE is an ongoing study comprised of 2 cohorts, Cohort A and Cohort B; only data for Cohort A are presented
- **Here we evaluate Cohort A Week 16 results comparing the efficacy of guselkumab (GUS) vs PBO, along with effects of treatment on health-related quality of life, as measured by the Psoriasis Symptoms and Signs Diary (PSSD)**

METHODS

VISIBLE Study Design



BSA=body surface area; GUS=guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=placebo; PSSD=Psoriasis Symptoms and Signs Diary.

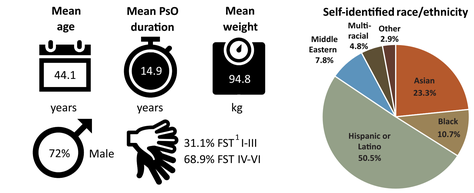
CONCLUSIONS

Clearer Skin

- **After 3 doses of GUS, a significantly greater proportion of participants achieved IGA 0/1 and PASI 90 vs PBO**
- **VISIBLE results will enable evidence-based medical decision-making and address additional unmet needs for psoriasis patients across all skin tones**

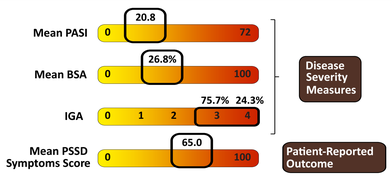
RESULTS

Baseline Demographics

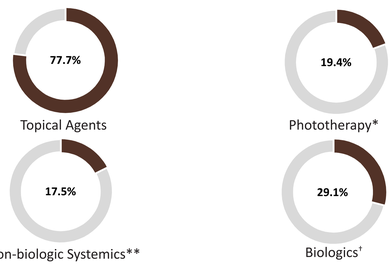


FST=Fitzpatrick skin type; PsO=psoriasis.

Baseline Disease Characteristics, N=103



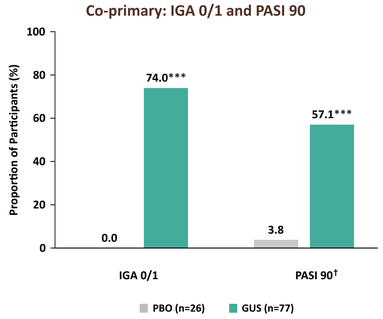
Previous PsO Medications/Therapies (% of Participants)



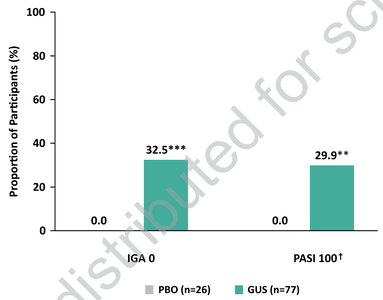
**Includes PUVA or UVB. **Includes PUVA, methotrexate, cyclosporine, acitretin. †Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab. BSA=body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsO=psoriasis; PSSD=Psoriasis Symptoms and Signs Diary; PUVA=psoralen plus ultraviolet A; UVB=ultraviolet B.*

Significantly greater proportions of participants in the GUS vs PBO group achieved the co-primary endpoints and achieved complete clearance at Week 16

Co-primary: IGA 0/1 and PASI 90

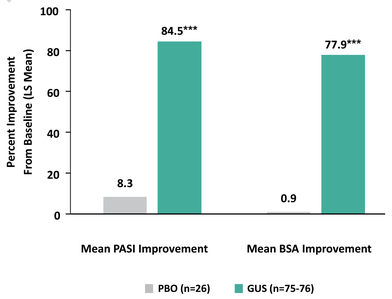


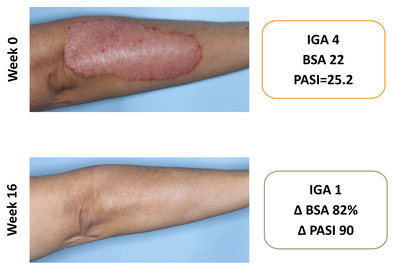
Complete Clearance



***p<0.01 vs PBO. ***p<0.001 vs PBO. p-values are based on Cochran-Mantel-Haenszel test stratified by FST I-III/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. †≥90% or =100% improvement from baseline in PASI. FST=Fitzpatrick skin type; GUS=guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=placebo; PsO=psoriasis.*

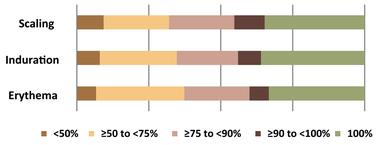
The GUS group achieved greater mean percent improvements from baseline in PASI and BSA vs the PBO group at Week 16



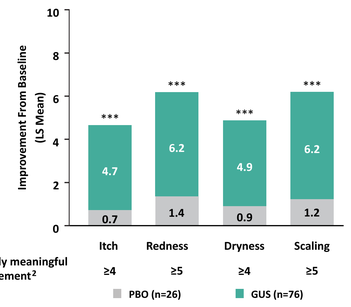


****p<0.001 vs PBO. LS means and p-values are based on MMRM. Zero change was assigned after participants discontinued study agent due to lack of efficacy/worsening of PsO or initiated a prohibited PsO treatment. Missing data were handled by MMRM under missing at random assumption. BSA=body surface area; GUS=guselkumab; IGA=Investigator's Global Assessment; LS=least square; MMRM=mixed model for repeated measures; PASI=Psoriasis Area and Severity Index; PBO=placebo; PsO=psoriasis.*

The proportions of GUS-treated participants achieving improvements in PASI components (scaling, induration, erythema) at Week 16 were similar



Greater mean improvements from baseline in overall PSSD symptom score were observed for the GUS group vs the PBO group (49.4 vs 8.2, p<0.001) at Week 16, with similar improvements in individual PSSD measures



****Nominal p<0.001 vs PBO. LS means and p-values are based on MMRM. GUS=guselkumab; LS=least square; PBO=placebo; MMRM=mixed model for repeated measures.*

- **Safety outcomes were consistent with the established safety profile of GUS**
- **No new safety signals were identified**

Key Safety Information Through Week 16

	PBO	GUS
Safety analysis set, n	26	77
Average duration of follow-up (weeks)	16.0	16.1
≥1 AE	5 (19.2%)	29 (37.7%)
Discontinued due to ≥1 AE*	0	1 (1.3%)
≥1 SAE	0	0
≥1 Injection site reactions	0	0
Infections	3 (11.5%)	16 (20.8%)
Serious infections	0	0
Malignancies (including NMSC)	0	0
Active TB	0	0
IBD	0	0
MACE	0	0
Deaths	0	0

*Data shown are n (%), unless otherwise indicated. *Participant discontinued due to impetigo and atopic dermatitis. Participants are counted only once for any given event, regardless of the number of times they actually experienced the event. AEs are coded using MedDRA version 25.1. AE=adverse event; GUS=guselkumab; IBD=inflammatory bowel disease; MACE=major adverse cardiovascular event; NMSC=nonmelanoma skin cancer; PBO=placebo; SAE=serious adverse event; TB=tuberculosis.*

References

1. Fitzpatrick TB, et al. *Arch Dermatol.* 1988;124(6):869-871.
2. Armstrong AW, et al. *J Dermatolog Treat.* 2019;30:27-34.

Disclosures

L. Stein Gold is an investigator/advisor and/or speaker for AbbVie, Amgen, Arctis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **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, Janssen, Leo, Medimmune, Novartis, Pfizer, Regeneron, Roche, Sanofi, Genzyme, Sun, Takeda, UCB, and Xenon. **A.O. Rodriguez** has served as an advisor and/or speaker for Arcutis, Dermavant, EPI Health, Janssen, Leo, Lilly, Novartis, Sciton, Sun Pharma, and UCB; owns stock in Strathspey Crown. **J. Vasquez, K. Rowland, O. Choi,** and **T. Alkousakis** are employees of Janssen Scientific Affairs, LLC, and **J. Jeyarajah** and **M. Petrick** are employees of Janssen Research & Development, LLC; employees may own stock/stock options in Johnson & Johnson. **J. Alonso-Llamazares** has served as speaker for Arcutis, Incyte, Eli Lilly, and UCB; as an advisor for Arcutis and Leo; and as an investigator for Amgen, Eli Lilly, Janssen, and Takeda. **S. Tyring** 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, Glenmark Pharma, IQVIA, Janssen, Kiniksa Pharma, Leo, Menlo Therapeutics, Merck, Novartis, Nycomed Amersham, Parexel, Quintiles Pharma, Regeneron Pharma, Sanofi, Trevi Therapeutics, UCB, and Vical. **A.W. Armstrong** has served as a research investigator and/or consultant for AbbVie, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, Janssen, KHK, Leo, Modernizing Medicine, Novartis, Ortho Dermatologics, Regeneron, Sanofi, Sun, and UCB.

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