VISIBLE: GUSELKUMAB IMPACT ON PSORIATIC ARTHRITIS AT WEEK 16 IN PARTICIPANTS WITH MODERATE-TO-SEVERE PSORIASIS ACROSS ALL SKIN TONES

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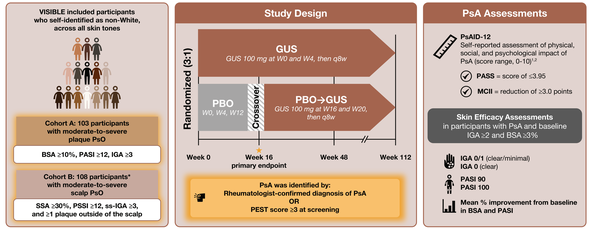
BACKGROUND

- **VISIBLE** is an ongoing Phase 3b study evaluating the efficacy and safety of **guselkumab** (GUS) in participants with moderate-to-severe plaque **psoriasis** (PsO) across all skin tones
- **Cohort A** enrolled participants with predominantly moderate-to-severe plaque PsO, and **Cohort B** enrolled participants with predominantly moderate-to-severe scalp PsO
- VISIBLE participants were evaluated for **PsA at screening**: PsA was identified based on a rheumatologist-confirmed diagnosis of PsA or a Psoriasis Epidemiology Screening Tool (PEST) score ≥3

OBJECTIVE/METHODS

Objective

This Week 16 post hoc analysis evaluates efficacy and patient-reported outcomes with GUS treatment in VISIBLE Cohort A and Cohort B participants with PsA at baseline



Cohort B efficacy analyses were performed for 102 participants who were correctly randomized. BSA=Body surface area; IGA=Investigator's Global Assessment; MCII=Minimal clinically important improvement; PASI 90/PASI 100= ≥90% or 100% improvement in Psoriasis Area and Severity Index; PASS=Patient Acceptable Symptom Score; PBO=Placebo; PsAID-12=Psoriatic Arthritis Impact of Disease-12; PSSI=Psoriasis Scalp Severity Index; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

CONCLUSIONS

At baseline, the majority of VISIBLE study participants with PsA had PsAID-12 scores above the PASS threshold, indicating the need for improved PsA control across all skin tones

After only 3 GUS doses, ~60% of these participants achieved clinically meaningful improvements in their PsA symptoms and health-related quality of life

Consistent with the overall VISIBLE population, the majority of GUS-treated participants with PsA achieved significantly clearer skin as assessed by IGA, PASI, and BSA measures

RESULTS

At baseline, 29.8% (61/205) of VISIBLE Cohort A and B participants had PsA

- Mean baseline data reflect moderate impact of PsA on health and extensive skin and scalp disease

Figure 1. Baseline Demographics

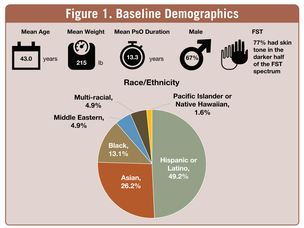
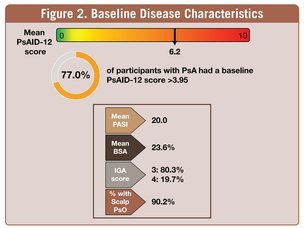


Figure 2. Baseline Disease Characteristics



FST=Fitzpatrick Skin Type; objective skin tone determined with colorimeter device measurement of non-sun exposed skin.

At Week 16, mean change from baseline in PsAID-12 was greater with GUS vs PBO, and mean improvement with GUS exceeded the MCII threshold of −3.0

Figure 3. Mean PsAID-12 Score at Baseline and Week 16

**nominal p<0.001 vs PBO. Δ=Least squares (LS) mean difference between baseline and Week 16 among participants with data at both timepoints. LS mean differences and p-values are based on an analysis of covariance model, with treatment group, baseline PsAID-12 score, and FST (I-III or IV-VI) as covariates; all p-values are nominal as this is a post hoc analysis. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening psoriasis, or initiated a prohibited psoriasis treatment prior to Week 16) were assigned a change from baseline=0. Missing data were not imputed.*

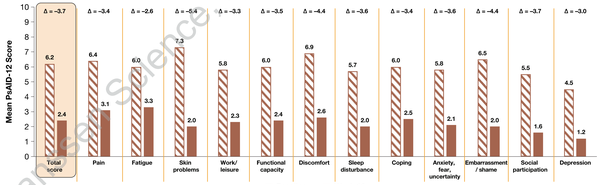
At Week 16, nearly 60% of GUS-treated participants with baseline PsAID-12 scores of >3.95 and ≥3.0, respectively, achieved PASS and MCII

Figure 4. Achievement of PsAID-12 Response Thresholds at Week 16

***nominal p≤0.01 vs PBO. p-values are based on Fisher's exact test; all p-values are nominal as this is a post hoc analysis. Participants meeting treatment failure criteria or with missing data were considered nonresponders. Achievement of PASS (PsAID-12 ≤3.95) was assessed for participants with PsAID-12 scores >3.95 at baseline. Achievement of MCII (reduction of ≥3 points) was assessed for participants with PsAID-12 scores ≥3.0 at baseline.*

GUS treatment provided meaningful improvements across all PsAID-12 domains

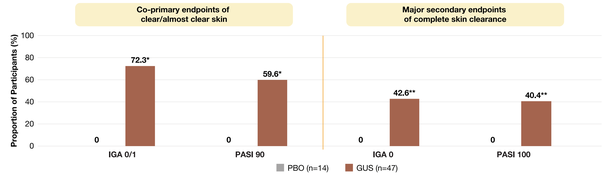
Figure 5. Improvements in PsAID-12 Component Scores From Baseline to Week 16 Among GUS-Treated Participants (n=40)



Δ=Mean change from baseline to Week 16.

At Week 16, 72% and 60% of GUS-treated participants with PsA at screening achieved the co-primary endpoints of IGA 0/1 and PASI 90, respectively, and >40% had complete skin clearance vs 0 in the PBO group

Figure 6. Achievement of Skin Efficacy Endpoints at Week 16 Among Participants With PsA at Screening and Baseline IGA ≥2 and BSA ≥3%



**nominal p<0.001 vs placebo. **nominal p≤0.01 vs placebo. p-values are based on Fisher's exact test; all p-values are nominal as this is a post hoc analysis. Participants meeting treatment failure criteria or with missing data were considered nonresponders.*

At Week 16, mean percent improvements from baseline in BSA and PASI were 84.8% and 86.9%, respectively, for GUS-treated participants with PsA at screening

Figure 7. Mean Percent Improvement in BSA and PASI From Baseline to Week 16

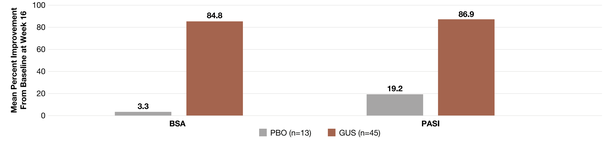


Figure 8. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16

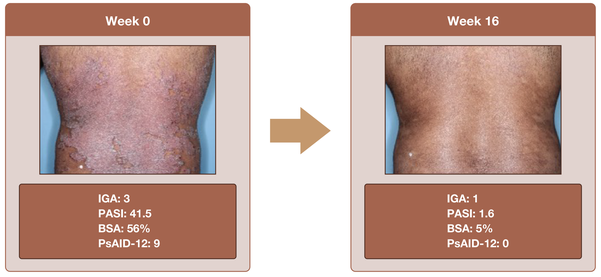
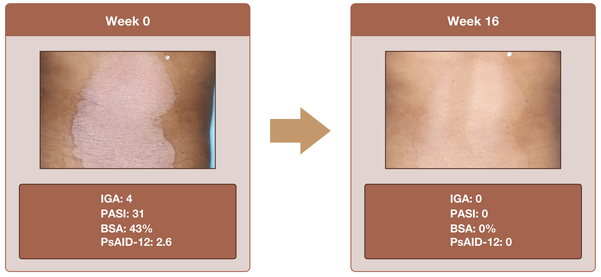


Figure 9. Participant Who Achieved IGA 0 and PASI 100 (Complete Clearance) at Week 16



References: 1. Gossec L, et al. *Ann Rheum Dis.* 2014;73:1012-9. **2.** Holland R, et al. *J Psoriasis Psoriatic Arthritis.* 2022;5:12-22. **Acknowledgments:** Medical writing support was provided by Cherie Koch, PhD, of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, 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 Janssen Scientific Affairs, LLC, a Johnson & Johnson company, Horsham, PA, USA. **Disclosures: ABG:** receives research/educational grants from Bristol Myers Squibb, Highlights Therapeutics, Janssen, and UCB Pharma (all paid to Mount Sinai School of Medicine); has received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Ayoltres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA). **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 received 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, and UCB. **OC, TA, DF, OA, SDC,** and **DC:** are employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, and stockholders of Johnson & Johnson. **JJ:** is an employee of Janssen Research & Development, LLC. **JFM:** is a consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte, Janssen, Leo Pharma, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB.

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