VISIBLE: GUSELKUMAB IMPACT ON PSORIATIC ARTHRITIS THROUGH WEEK 48 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 **psoriatic arthritis (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

This Week 48 post hoc analysis evaluates efficacy and patient-reported outcomes with GUS treatment in all VISIBLE participants with PsA at baseline (n=61; 29.8%)[a]

VISIBLE included participants who self-identified as non-white, across all objectively measured skin tones

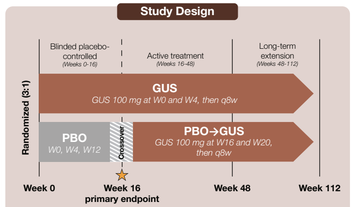
Cohort A: 103 participants with moderate-to-severe plaque PsO

BSA ≥10%, PASI ≥12, IGA ≥3

Cohort B: 108 participants[b] with moderate-to-severe scalp PsO

SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 plaque outside of the scalp

Study Design



PsA Assessments

PsAID-12 was used for those identified to have PsA at screening

PsAID-12 is a self-reported assessment of physical, social, and psychological impact of PsA (score range, 0-10)[1,2]

- **PASS** = score of ≤3.95
- **MCII** = reduction of ≥3.0 points

Skin Efficacy Assessments
in participants with PsA and baseline IGA ≥2 and BSA ≥3%

- **IGA 0/1** (clear/minimal) **IGA 0** (clear)
- **PASI 90 PASI 100**
- **Mean % improvement in BSA and PASI**

[a]Efficacy Analysis Set: VISIBLE Cohorts A and B, 29.8% (n=61) had PsA. IGA ≥2 and PASI ≥3 at baseline. [b]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.

RESULTS

At baseline, 29.8% (61/205) of VISIBLE participants had PsA

- Mean baseline data reflect moderate symptoms and impacts of PsA based on PsAID-12 scores, and extensive skin and scalp disease

Figure 1. Baseline Demographics

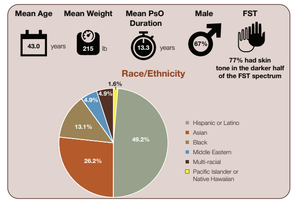
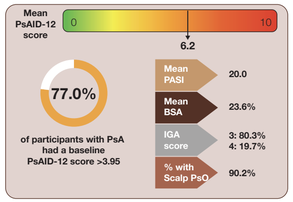


Figure 2. Baseline Disease Characteristics

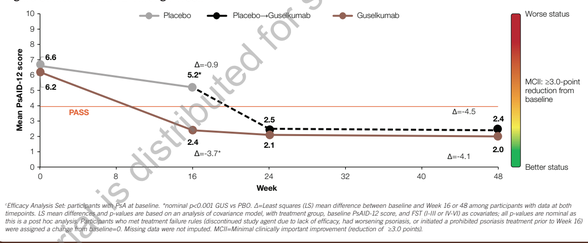


Self-identified Backgrounds and FST in VISIBLE Cohort A and B	I	II	III	IV	V	VI
Black (n=24)						
African American (n=18)						
American Indian or Alaska Native (n=1)						
Asian (n=63)						
East Asian (n=14)						
Filipino (n=7)						
South Asian (n=22)						
Southeast Asian (n=20)						
Non-White Hispanic or Latino (n=94)						
Central American (n=9)						
Cuban (n=13)						
Mexican (n=50)						
Puerto Rican (n=5)						
South American (n=15)						
Middle Eastern (n=13)						
Native Hawaiian or Pacific Islander (n=1)						
Multiracial (n=12)						
Other (n=3)						

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 PsAID-12 improvement with GUS exceeded the MCII threshold of −3.0, which further improved through Week 48

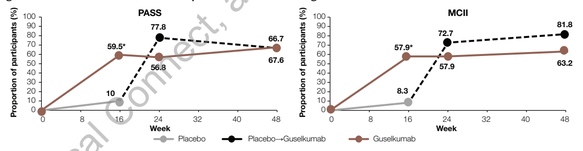
Figure 3. Mean PsAID-12 Through Week 48[c]



[c]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.001 GUS vs PBO. Δ=Least squares (LS) mean difference between baseline and Week 16 or 48 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. MCII=Minimal clinically important improvement (reduction of ≥3.0 points).

At Week 48, more than 60% of GUS-treated participants with PsA and baseline PsAID-12 scores of >3.95 and ≥3.0, respectively, achieved PASS and MCII

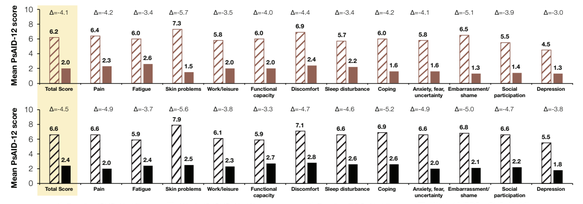
Figure 4. Achievement of PsAID-12 Response Thresholds Through Week 48[d]



[d]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.05 GUS vs PBO. 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. MCII=Minimal clinically important improvement (reduction of ≥3.0 points). PASS=Patient Acceptable Symptom Score (score of ≤3.95).

GUS treatment provided meaningful improvements across all PsAID-12 domains

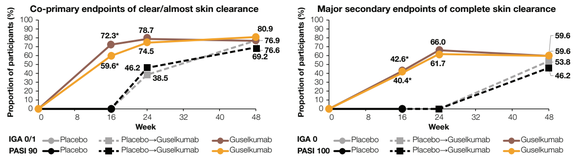
Figure 5. Improvements in PsAID-12 Component Scores From Baseline to Week 48 Among GUS-Treated Participants and Week 16 PBO→GUS Crossover Participants[e]



[e]Efficacy Analysis Set: participants with PsA at baseline. Δ=Mean change from baseline to Week 48. 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. For participants who were randomized to placebo at Week 0, only those participants who crossed over to guselkumab at or after Week 16 were included in Week 48 analysis.

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

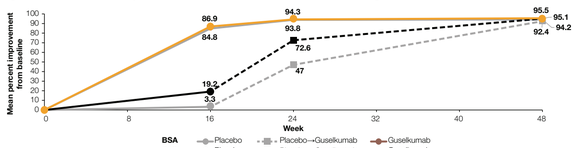
Figure 6. Achievement of Skin Efficacy Endpoints Through Week 48 Among Participants With PsA at Screening and Baseline IGA ≥2 and BSA ≥3%[f]



[f]Efficacy Analysis Set: participants with PsA at baseline. *nominal p<0.05 GUS vs PBO. p-values are based on Fisher's exact test. Participants meeting treatment failure criteria or with missing data were considered nonresponders.

At Week 48, mean percent improvements from baseline in BSA and PASI were above 92% for GUS-treated participants with PsA at screening[g]

Figure 7. Mean Percent Improvement in BSA and PASI From Baseline Through Week 48



[g]Efficacy Analysis Set: participants with PsA at baseline. 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. For participants who were randomized to placebo at Week 0, only those participants who crossed over to guselkumab at or after Week 16 were included.

Figure 8. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16 and at Week 48

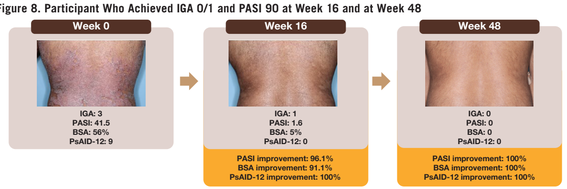
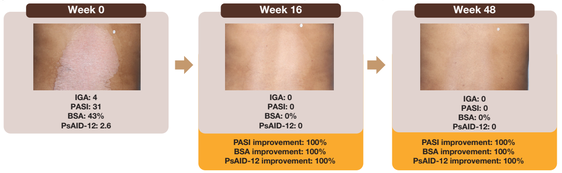


Figure 9. Participants Who Achieved IGA 0 and PASI 100 (Complete Clearance) at Week 16 and at Week 48



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
- After only 3 GUS doses, ~60% of these participants achieved clinically meaningful improvements in their PsA symptoms and health-related quality of life; these improvements continued and were maintained through Week 48
- Consistent with the overall VISIBLE population, the majority of GUS-treated participants with PsA achieved notably clearer skin as assessed by IGA, PASI, and BSA measures; the VISIBLE study is still ongoing

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References: 1. Gossec, L, et al. *Ann Rheum Dis.* 2014;73:1012-9. **2.** Holland R, et al. *J Psoriasis Psoriatic Arthritis.* 2020;5:12-22. **Acknowledgments:** Medical writing support was provided by Cherie Koch, PhD, an employee of Johnson & Johnson, and Jackie Johnson, PhD, an employee of Certara, 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. **Disclosures: ABG:** receives research/educational grants from Bristol Myers Squibb, Janssen, Moonlake, and UCB Pharma, (all paid to Mount Sinai School of Medicine), and she has received honoraria as an advisory board member and consultant for Amgen, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva, UCB, and Xbiotech (stock options for RA). **AM:** has received grants (funds to institution) and honoraria as consultant/advisor for AbbVie, Almirall, Arcutis, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, Johnson & Johnson, L'Oréal, Nutrafol, Pfizer, Revian, Sanofi-Genzyme, UCB. **TB:** is currently a principal investigator for studies being sponsored by AbbVie, Castle, CorEvitas, Dermavant, Galderma, Mindera, and Pfizer. She has additional research funding from Novartis and Regeneron. She 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, KR, SDC, JV, TM,** and **DC** are employees and stockholders of Johnson & Johnson. **AN:** has served as a speaker, investigator, and/or consultant for AbbVie, Almirall, Amgen, Arcutis, ASLAN, Beiersdorf, BI, BMS, Dermira, Dermavant, EPI, Galderma, Incyte, ISDIN, Janssen, Lilly, Leo, Mayne, Novan, Novartis, Ortho-Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **SD:** serves as a consultant and/or investigator for a variety of different organizations including Eli Lilly, Galderma, Incyte, Janssen, L'Oréal, Pfizer and others. He also serves in numerous leadership capacities within Dermatology. **AA:** has received grants (funds to institution) from AbbVie, Amgen, Arcutis, Castle, Dermavant, Galderma, Incyte, and LEO; has served on an advisory board or consulted for AbbVie, Allergan, Almirall, Alphyn, Amgen, Apogee, Arcutis, Avita Medical, Bausch Health, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Canfield, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Genentech, Genzyme, Incyte, Janssen, LEO, L'Oréal, Ortho, Pfizer, Sanofi-Regeneron, Swiss American, UCB, and VisualDx; has served as a speaker for Aerolase, 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. **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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