VISIBLE COHORT B: GUSELKUMAB IMPROVES SCALING, ITCH, AND SHEDDING OR FLAKING THROUGH WEEK 48 IN PARTICIPANTS WITH MODERATE-TO-SEVERE SCALP PSORIASIS

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BACKGROUND

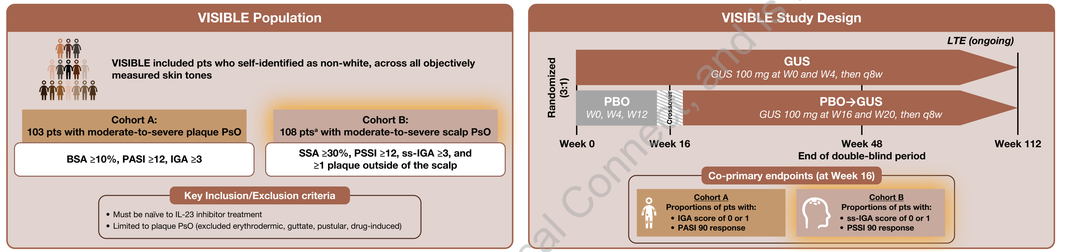
- VISIBLE is an ongoing Phase 3b, randomized, double-blind, placebo (PBO)-controlled study of guselkumab (GUS) in participants with skin of color, across all objectively measured skin tones, with moderate-to-severe plaque psoriasis (PsO)
- Scaling, flaking, and itch directly impact quality of life in people with scalp PsO and affect work and interpersonal relationships due to feelings of embarrassment and restriction of clothing choices[1]

OBJECTIVES

- To evaluate investigator- and participant-reported scalp PsO-related assessments of scaling, itch, and shedding or flaking through Week 48 in VISIBLE Cohort B participants with moderate-to-severe scalp PsO

METHODS

Figure 1. VISIBLE Population and Study Design



[a]Efficacy was assessed in all participants who met Cohort B inclusion criteria (N=102). BSA=Body surface area; IGA=Investigator's Global Assessment; IL-23=Interleukin-23; LTE=long-term extension; PASI=Psoriasis Area and Severity Index; PSSI=Psoriasis Scalp Severity Index; pts=Participants; q8w=Every 8 weeks; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

OUTCOMES

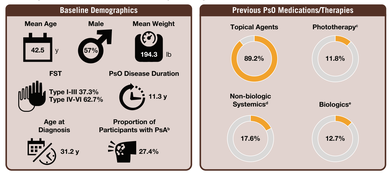
- Psoriasis Scalp Severity Index (PSSI)
  - Includes investigator-reported measures of erythema, induration, desquamation (scaling), and surface area of disease
  - Scaling was assessed at baseline and at Weeks 4, 12, 16, 20, 24, 32, 44, and 48
- Psoriasis Symptoms and Signs Diary (PSSD)
  - Includes participant-reported signs of Scaling and Shedding/Flaking and symptom of Itch in the past 7 days, scored from 0-10
  - Assessments at baseline, Weeks 4, 12, and every 4 weeks thereafter

RESULTS

Baseline Demographics and Disease Characteristics

- Baseline disease severity, as measured by ss-IGA, PSSI, and SSA, reflects extensive moderate-to-severe scalp disease.
- Despite the degree of disease severity, <20% had any previous exposure to systemic therapy (**Figure 2**).

Figure 2. Baseline Demographics and Previous PsO Medications/Therapies: Cohort B, Efficacy Analysis Set (N=102)



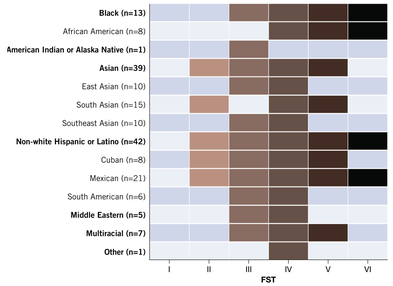
Data shown are mean (SD), unless otherwise indicated. [a]Participants with PsA had rheumatologist-confirmed PsA or score ≥3 on the Psoriasis Epidemiology Screening Tool at screening. [b]Includes PUVA or UVB. [c]Includes PUVA, methotrexate, cyclosporine, acitretin. [d]Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab. FST=Fitzpatrick skin type; PsA=Psoriatic arthritis; PUVA=Psoralen plus ultraviolet A; UVB=Ultraviolet B.

Table 1. Baseline Disease Characteristics: Cohort B

Efficacy analysis set, n	102
PASI (0-72)	14.6 (9.3)
BSA (%)	16.6 (14.4)
ss-IGA, n (%)	
Moderate (3)	84 (82.4%)
Severe (4)	18 (17.6%)
PSSI (0-72)	34.3 (13.2)
SSA (%)	59.8 (26.0)
PSSD symptoms score (0-100)	63.4 (23.6)
PSSD itch score (0-10)	7.8 (2.1)

Data shown are mean (SD), unless otherwise indicated.

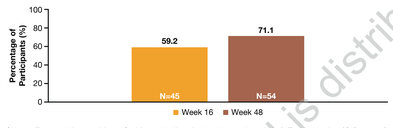
Figure 3. Race/Ethnicity and Fitzpatrick Skin Type: Cohort B, All Randomized Participants (N=108)



Subcategories shown were reported in >5 participants.

By Week 16, the majority of participants randomized to GUS achieved investigator-rated PSSI scaling score of 0, indicating absence of scaling

Figure 4. GUS-Randomized Participants (N=76)[f] Achieving PSSI Scaling=0



[f]Among efficacy analysis set participants. 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.

By Week 48, almost half of participants receiving GUS achieved self-reported absence of scalp symptoms (scaling and shedding/flaking)

Figure 5. GUS-Randomized Participants (N=75)[g] Achieving PSSD Scaling=0

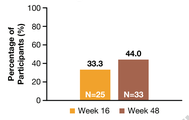
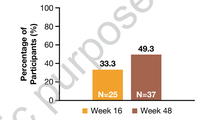


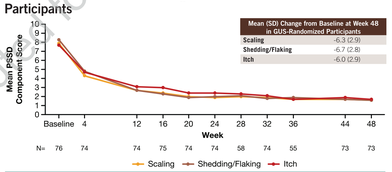
Figure 6. GUS-Randomized Participants (N=75)[h] Achieving PSSD Shedding/Flaking=0



[g]Among efficacy analysis set participants with PSSD scaling score >1 at baseline. [h]Among efficacy analysis set participants with PSSD shedding/flaking score ≥1 at baseline. 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.

After 2 doses, clinically meaningful improvements were seen in PSSD itch, scaling, and shedding/flaking in participants randomized to GUS

Figure 7. PSSD Scores Through Week 48 in GUS-Randomized Participants



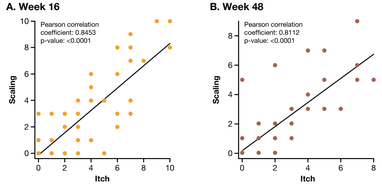
Mean (SD) Change from Baseline at Week 48 in GUS-Randomized Participants	
Scaling	-6.3 (2.9)
Shedding/Flaking	-6.7 (2.8)
Itch	-6.0 (2.9)

Clinically meaningful improvements from baseline are changes of ≥4 points for itch and ≥5 points for scaling and shedding/flaking[i]

When participants discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, 0 change from baseline was assigned from that point onward. Missing data were not imputed.

Strong correlations were observed between PSSD itch and PSSD scaling through Week 48

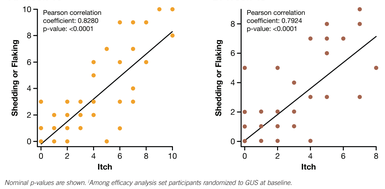
Figure 8. Correlation Between PSSD Itch and PSSD Scaling in GUS-Randomized Participants[i]



Nominal p-values are shown. [i]Among efficacy analysis set participants randomized to GUS at baseline.

Strong correlations were observed between PSSD Itch and PSSD Shedding/Flaking through Week 48

Figure 9. Correlation Between PSSD Itch and PSSD Shedding/Flaking in GUS-Randomized Participants[i]



Nominal p-values are shown. [i]Among efficacy analysis set participants randomized to GUS at baseline.

Figure 10. Participant Who Achieved Complete Scalp Clearance (PSSI 100) at Week 48

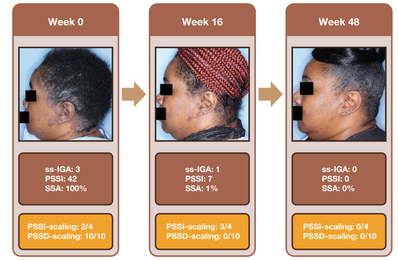


Figure 11. Participant Who Achieved Complete Scalp Clearance (PSSI 100) at Week 16 and Week 48

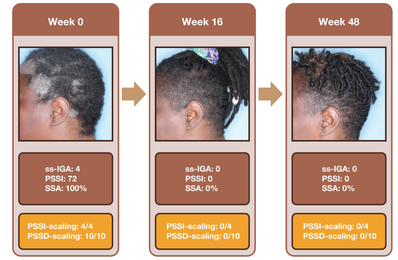
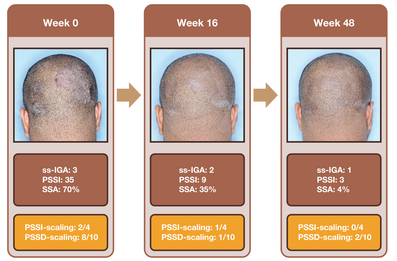


Figure 12. Participant Who Did Not Achieve Complete Scalp Clearance at Week 48



CONCLUSIONS

- **Both investigators and participants reported consistent, clinically meaningful improvements in scalp psoriasis-related scaling, itching, and shedding/flaking through 1 year of treatment with guselkumab**
- **Almost half of participants reported complete absence of scaling and shedding/flaking of their scalp at 48 weeks**

References: 1. Merola JF, Qureshi A, Husni ME. *Dermatol Ther.* 2018 May;31(3):e12589. **2.** Armstrong A, et al. *J. Dermatol. Treat.* 2019;30(1):27-34. **Acknowledgements:** Medical writing support was provided by Peijia (Jessica) Yuan, PhD, of Joulé Inc, funded by Johnson & Johnson, under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298-1304). Supported by Johnson & Johnson, Horsham, PA, USA. **Disclosures: D. Ruiz DaSilva** is a consultant and/or speaker for AbbVie, Arcutis, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, LEO Pharma, Pfizer, Sanofi, Regeneron, UCB, and Verrica. **R. Seervai** is a member of the Derm In-Review Advisory Council (DIRAC). **J.K. Tung** is or has been a clinical trials investigator, consultant, or speaker for AbbVie, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Eli Lilly, Galderma, Incyte, Johnson & Johnson, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB. **S.G. Kwatra** is an advisory board member/consultant for AbbVie, Amgen, Arcutis, Aslan, Bristol Myers Squibb, Cara, Castle Biosciences, Dermavant, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Regeneron, and Sanofi and has served as an investigator for Galderma, Incyte, Pfizer, and Sanofi. **A. McMichael** has received grants (funds to institution) and/or served as a consultant/advisor for AbbVie, Almirall, Arcutis, Bristol Myers Squibb, Eli Lilly, Galderma, Johnson & Johnson, Kenvue, L'Oréal, Nutrafol, Pfizer, Revian, Sanofi-Genzyme, and UCB. **T. Alkousakis, D. Chan, K. Rowland,** and **T. Ma** are employees and may be shareholders of Johnson & Johnson. **O. Choi** is a former employee of Johnson & Johnson. **PREVIOUSLY PRESENTED AT:** Winter Clinical Dermatology Conference; February 14-19, 2025; Big Island, Waikoloa Village, HI, USA.

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