

VISIBLE COHORT B: LONG-TERM PATIENT-REPORTED OUTCOMES THROUGH WEEK 100 IN PARTICIPANTS WITH MODERATE-TO-SEVERE SCALP PSORIASIS

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BACKGROUND

VISIBLE, a phase 3b, multicenter, randomized, double-blind, placebo (PBO)-controlled clinical trial, evaluated the efficacy and safety of guselkumab (GUS) in participants (pts) with moderate-to-severe plaque psoriasis (PsO) across all skin tones

VISIBLE included two cohorts:

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

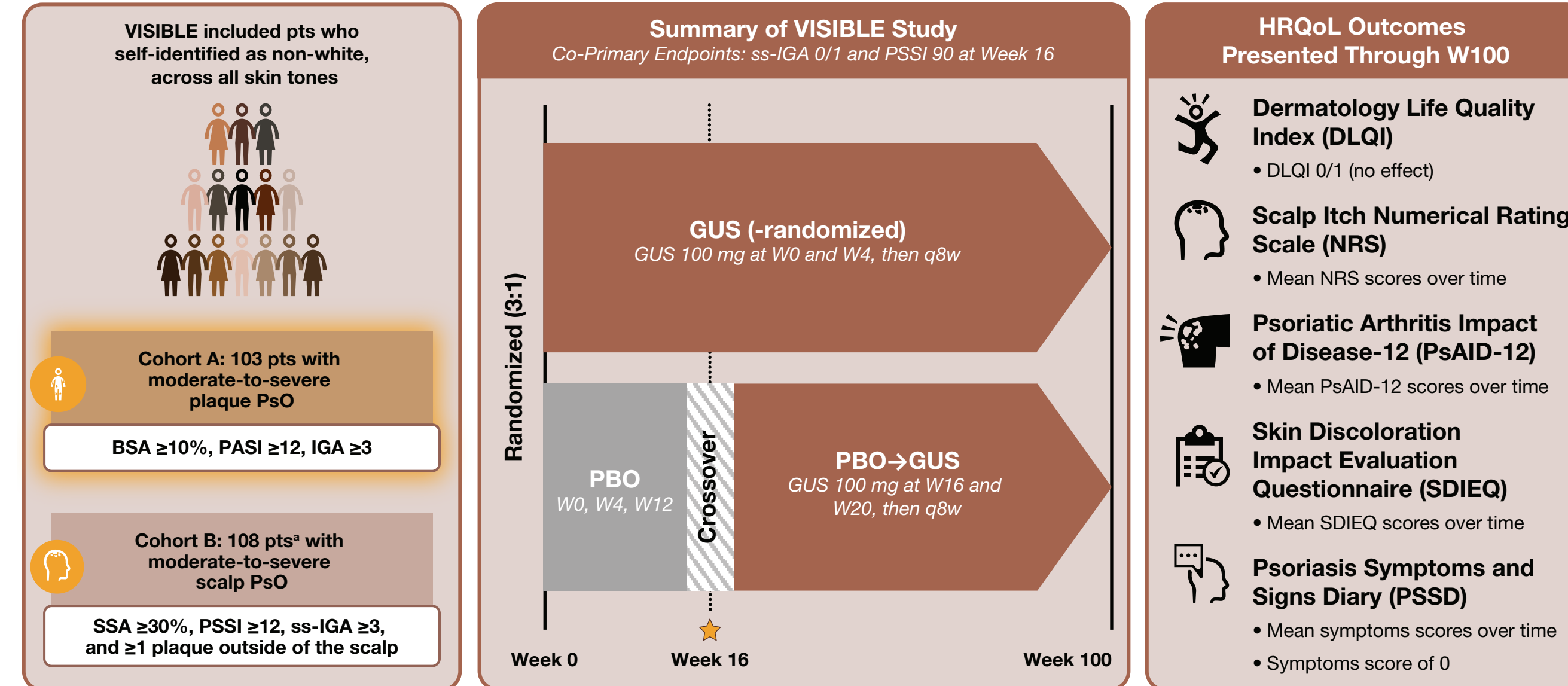
Scalp is the most commonly involved high-impact site among patients with moderate-to-severe plaque PsO, especially among those with skin of color (SOC), and scalp PsO is associated with increased risk of psoriatic arthritis (PsA)

- Scalp PsO can negatively impact daily life, with symptoms and signs including pruritus, intense scaling, and even alopecia, causing great physical and social distress¹
- Patients with PsO and SOC have reported a disproportionately greater impact of PsO on their health-related quality of life (HRQoL)^{2,3}

OBJECTIVE/METHODS

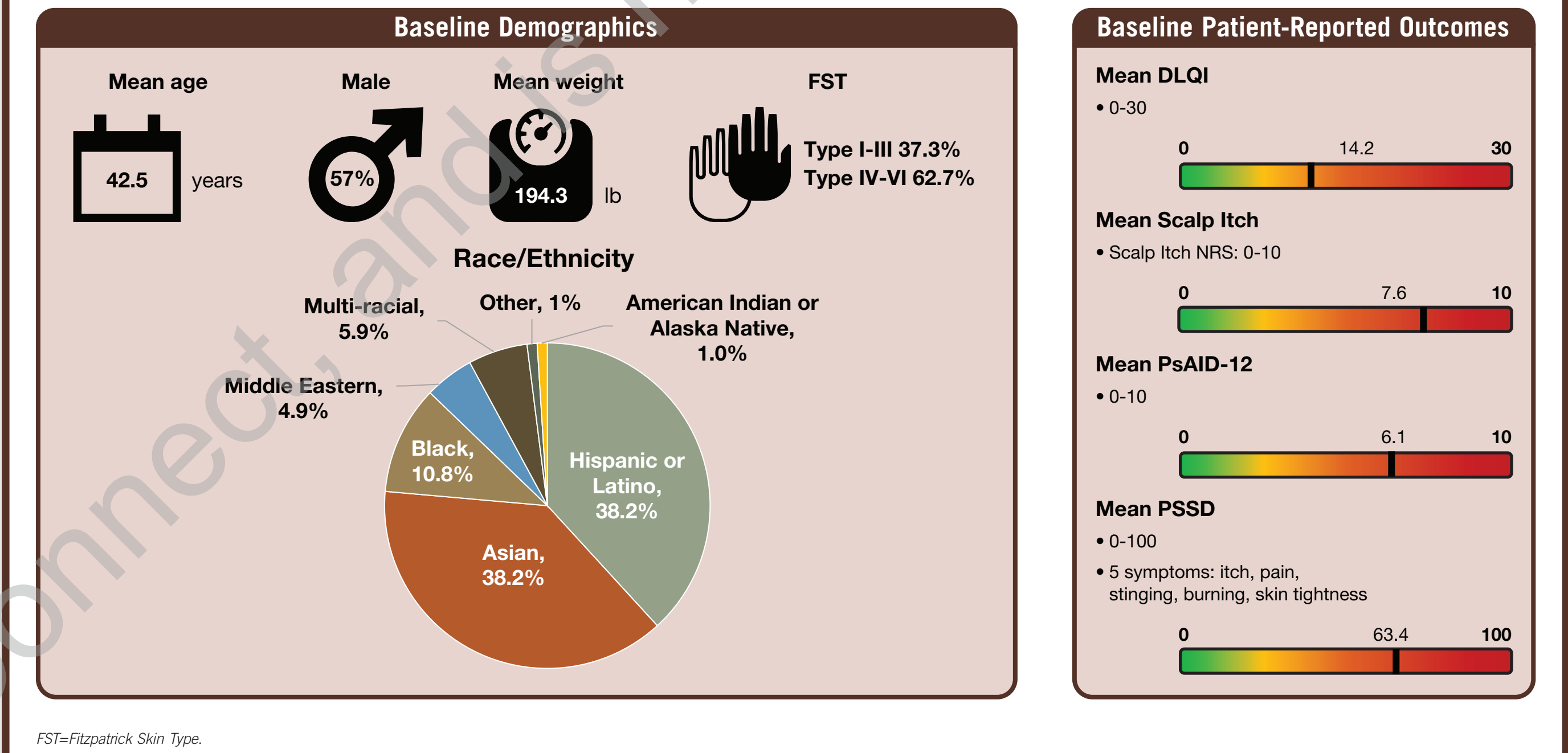
Objective

Assess the impact of GUS on patient-reported scalp PsO symptoms and HRQoL in Cohort B* through W100



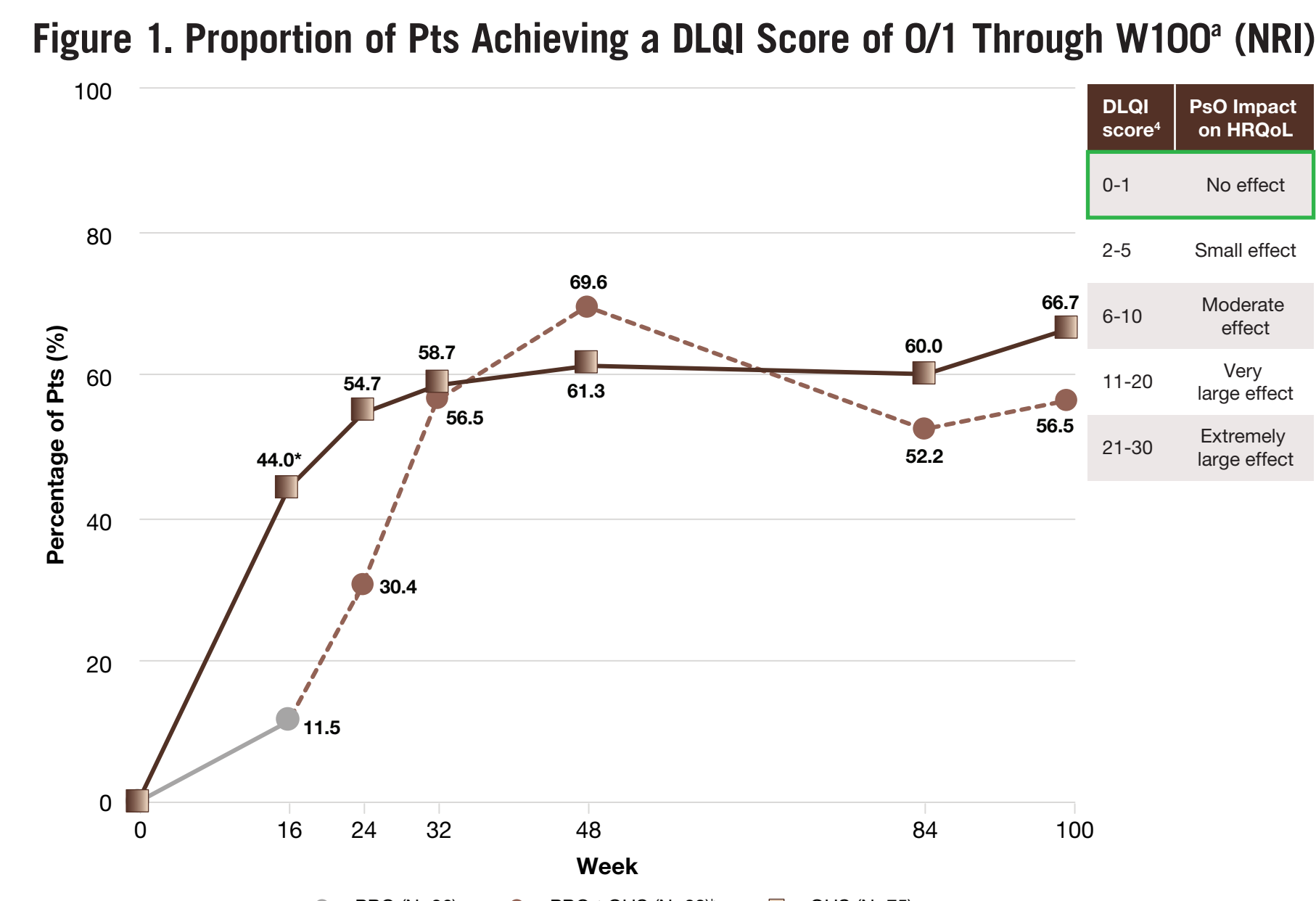
SSA=Scalp surface area; IGA=Investigator's Global Assessment; PSSI=Psoriasis Area and Severity Index; PSSI=Psoriasis Scalp Severity Index; q8w=Every 8 weeks; ss-IGA=Scalp-specific Investigator's Global Assessment. *Outcomes were assessed in all eligible Cohort B pts (N=102).

COHORT B BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS (N=102)



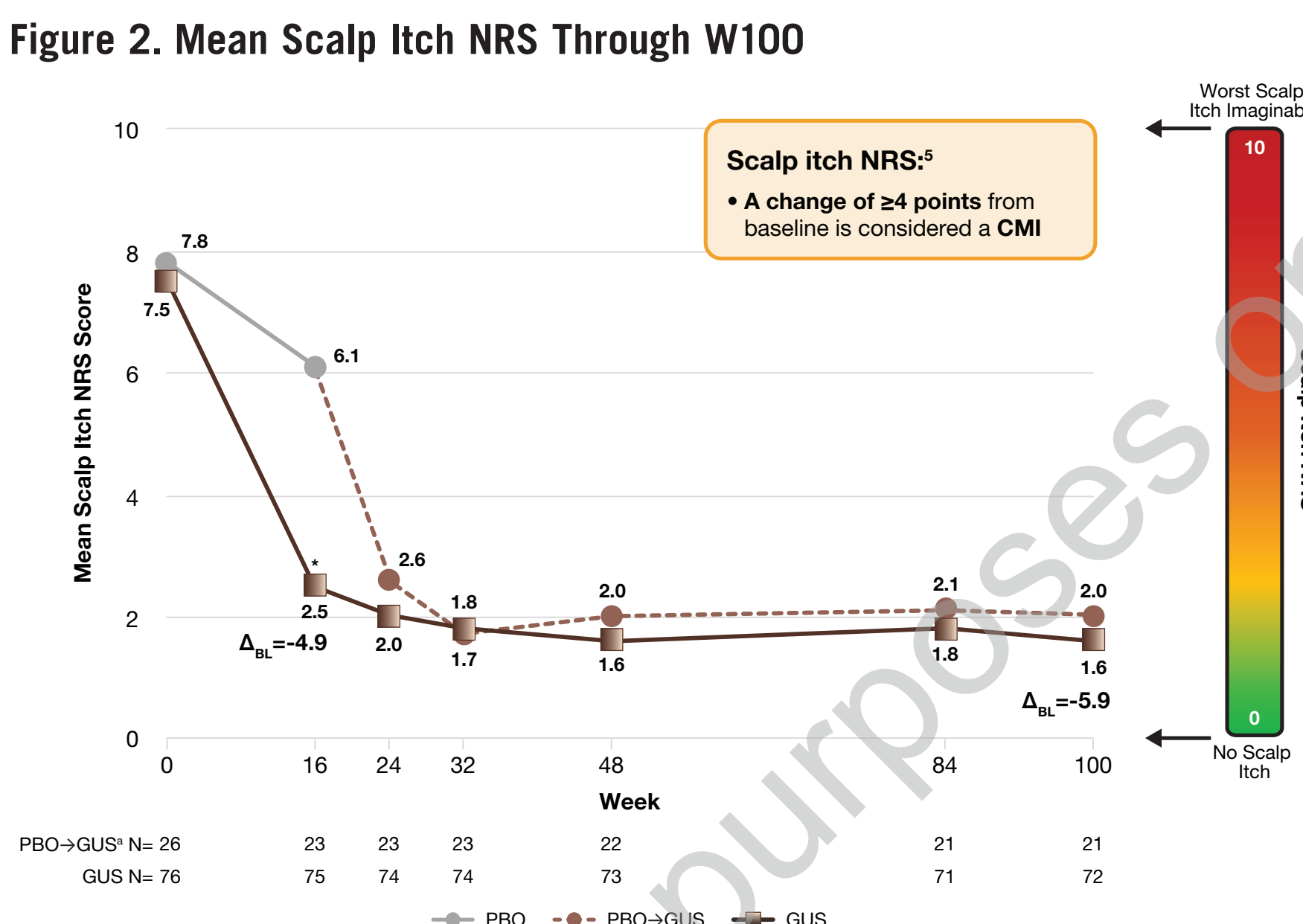
RESULTS

Approximately 45% of GUS-randomized pts reported no effect of PsO on their QoL by W16, with over 60% achieving and sustaining this endpoint through W100



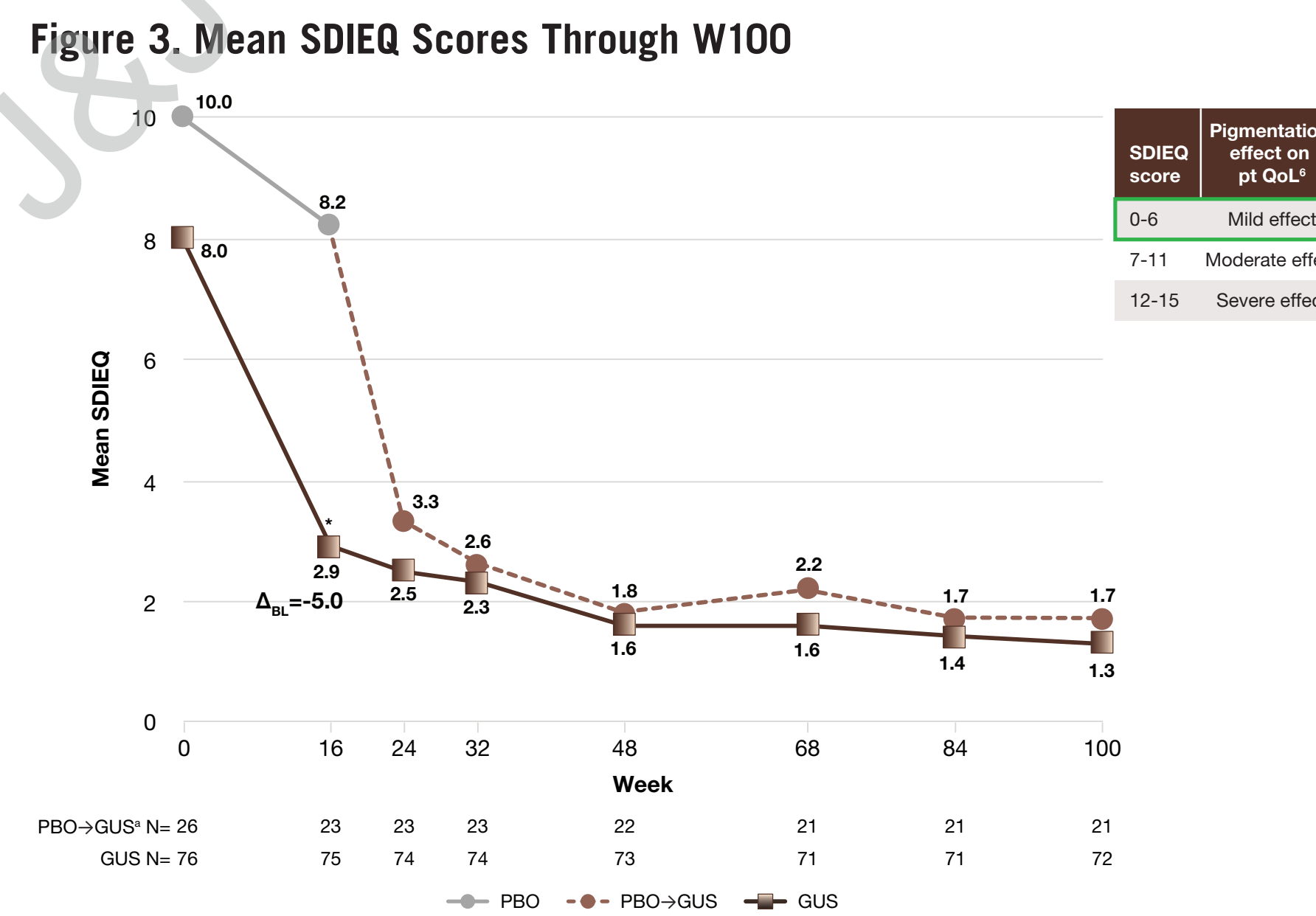
*Nominal p<0.003 vs PBO; p-values were based on the Cochran-Mantel-Haenszel χ^2 test stratified by FST (Type I-III/Type IV-VI). *Among pts with baseline DLQI >1. *For pts who were randomized to PBO at W0, only those pts who crossed over to GUS at or after W16 were included. *Pts who discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment prior to a designated study visit were considered not to have achieved the binary end point, and NRI was used for missing data. NRI=Nonresponder imputation.

By W16, meaningful improvement in mean scalp itch NRS was achieved in the GUS-randomized group, and was sustained through W100



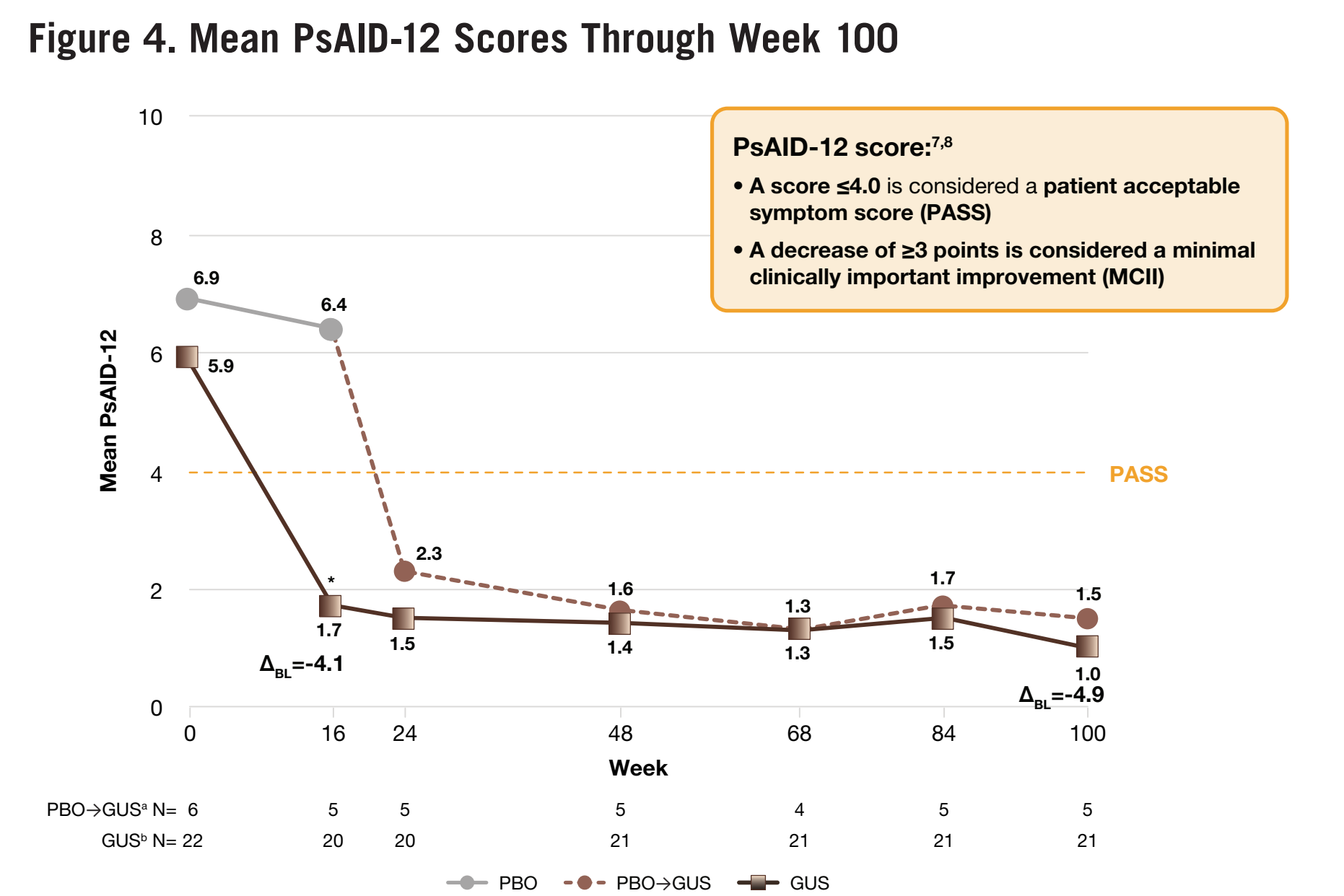
*Nominal p<0.001 vs PBO; p-values were based on the mixed model for repeated measures; explanatory variables included treatment group, visit, baseline score, FST (Type I-III/Type IV-VI), an interaction term of visit with treatment group, and an interaction term of visit with baseline score. *For pts who were randomized to PBO at W0, only those pts who crossed over to GUS at or after W16 were included. Baseline values were assigned if pts discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment (intercurrent events). Δ_{ss} =Mean improvement from baseline; zero change from baseline was assigned if pts discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment (intercurrent events).

Mean SDIEQ score, reflecting the effect of pigmentation on QoL, improved from the moderate to the mild range by W16 in the GUS-randomized group; improvements in mean SDIEQ continued and were sustained through W100



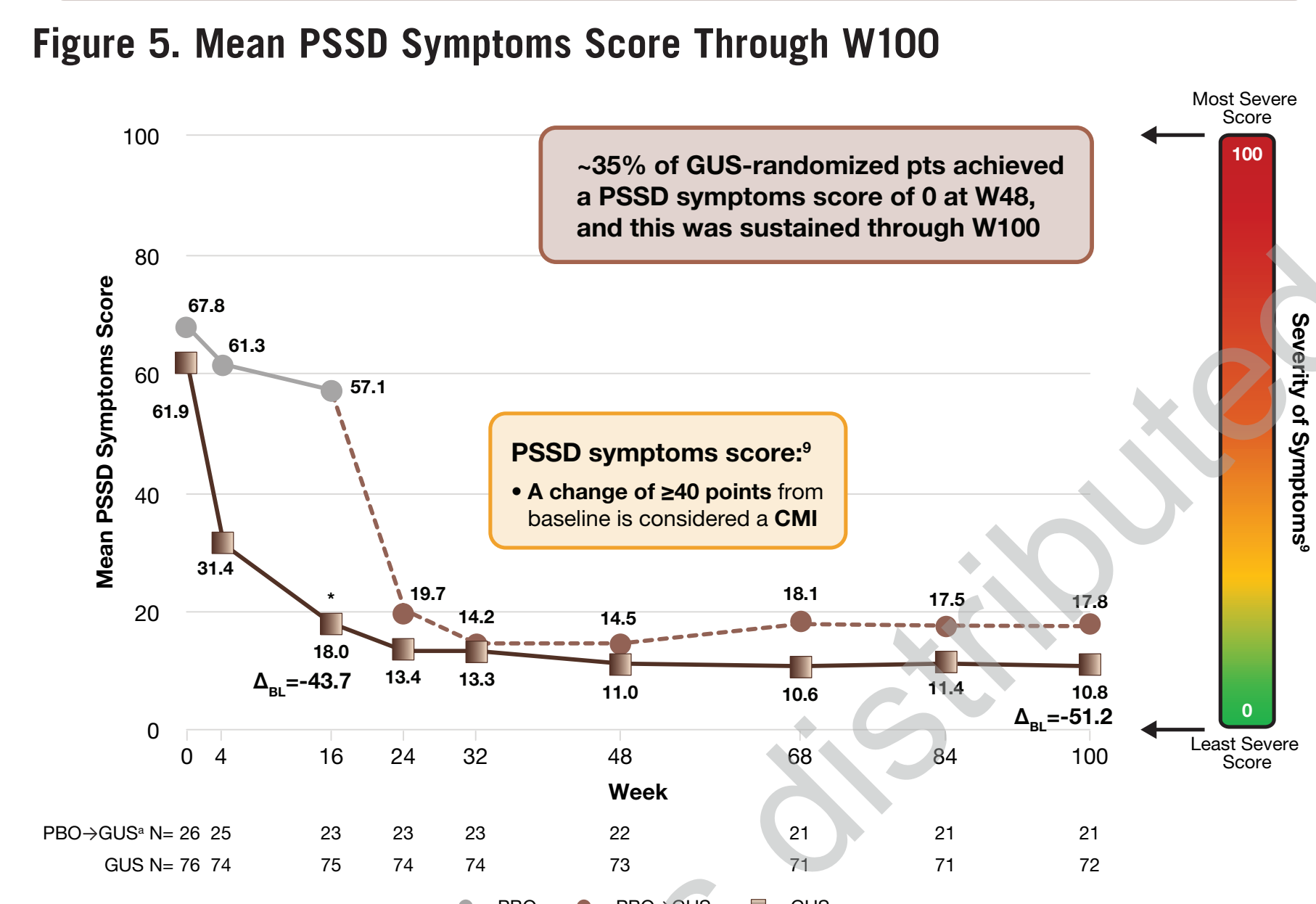
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By W16, mean PsAID-12 score, reflecting PsA symptoms, improved to a patient acceptable level in the GUS-randomized group, and improvements were sustained through W100



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Meaningful improvements in signs and symptoms of PsO were observed by W16 in the majority of GUS-randomized pts; improvements were sustained through W100

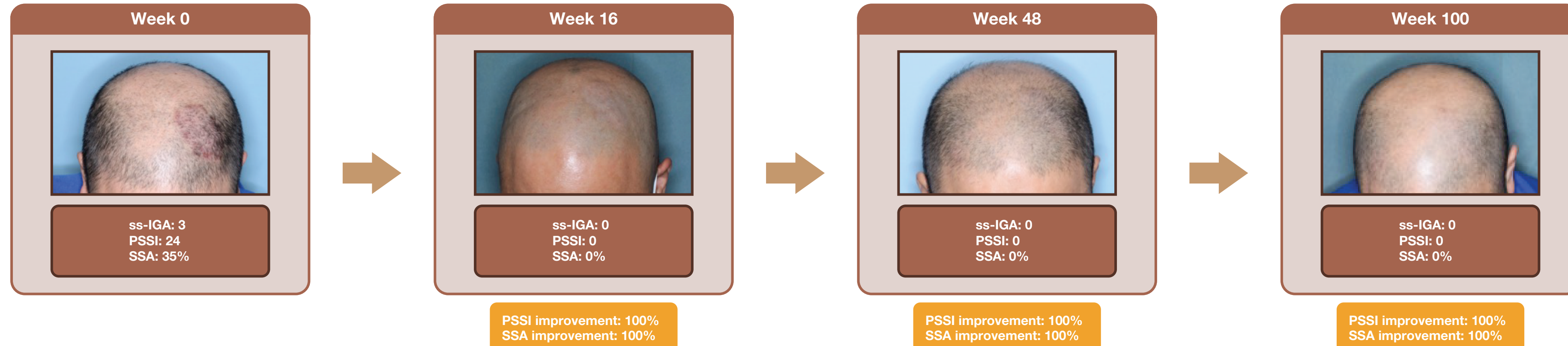


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Pt Who Achieved Complete Scalp Clearance (ss-IGA 0 and PSSI 100) by W16 and sustained response through W100



Pt Who Achieved Complete Scalp Clearance (ss-IGA 0 and PSSI 100) by W16 and sustained response through W100



CONCLUSIONS

Patient-reported outcomes assessing QoL, scalp PsO symptoms, impact of skin dyspigmentation, and PsA symptoms improved substantially by W16; improvements were generally sustained or improved through W100

These results support the effectiveness of GUS for reducing the impact of moderate-to-severe scalp PsO in patients, including those with PsA, across all skin tones over time

Reference: 1. Crowley J. *J Drugs Dermatol*. 2010;9:912-8. 2. Alexis AF & Blackcloud P. *J Clin Aesthet Dermatol* 2014 Nov;7(11):16-24. 3. Takeshita J, et al. *J Invest Dermatol* 2022 Sep;142(9):2528-2531.e3. 4. Hongbo Y, et al. *J Invest Dermatol*. 2005;125:659-64. 5. Wang Y, et al. *J Dermatolog Treat*. 2019;30:775-83. 6. Maymone MBC, et al. *J Dermatol*. 2018;45:361-2. 7. Gossec L, et al. *Ann Rheum Dis*. 2014;73:1012-9. 8. Holland R, et al. *J Psoriasis Psoriatic Arthritis*. 2022;5:12-22. 9. Armstrong A, et al. *Dermatolog Treat*. 2019;30:27-34. **Acknowledgments:** Medical writing support was provided by Peijia (Jessica) Yuan, PhD, of Janssen 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:** A McMichael has received grants (funds to institution) and/or served as consultant/advisor for AbbVie, Almiral, Arcutis, Bristol Myers Squibb, Eli Lilly, Galderma, Johnson & Johnson, Kenvue, L'Oréal, Nutrafol, Pfizer, Revian, Sanofi-Genzyme, and UCB. T Bhutani is currently a principal investigator for studies being sponsored by AbbVie, Castle, CorEvitas, Dermavant, Galderma, Mindera, and Pfizer; has additional research funding from Novartis and Regeneron; has served as an advisor for AbbVie, Arcutis, Boehringer-Ingelheim, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, LEO, Pfizer, Novartis, Sun, and UCB. S Smith receives honoraria and research grants from AbbVie, Almiral, Alumis, Amgen, Arcutis, Calix, Candesant, Eli Lilly, Endo Pharmaceuticals, Galderma, Johnson & Johnson, Moberg, Nielsen, Pfizer, Sun, and Tencate. O Choi was an employee of Johnson & Johnson at the time this work was conducted and is a shareholder of Johnson & Johnson; she is currently an employee of Apogee Therapeutics. T Alkousakis, D Chan, and T Ma are employees of Johnson & Johnson; employees may own stock/options in Johnson & Johnson. R Radusky is a principal investigator for AbbVie, Amgen, Eli Lilly, Incyte, Jasper Pharmaceutical, Johnson & Johnson, Pfizer, and Sanofi. J Yeung has served as a speaker/consultant/honorarystudy for AbbVie, Amgen, Anacor, Arcutis, Astella, Bausch, Baxalta, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Eli Lilly, Forward, Galderma, Johnson & Johnson, LEO, MedImmune, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Sun, Takeda, UCB, and Xenon. G Han is a consultant, speaker, or received research support from AbbVie, Amgen, Athenex, Beiersdorf, Bristol Myers Squibb, Boehringer Ingelheim, Bond Avillion, Castle Biosciences, Celgene, CerVe, Dermavant, DermTech, Eli Lilly, Johnson & Johnson, LEO, MC2, MedX, Novartis, Ortho Dermatologics, Pfizer, Regeneron/Sanofi, Sun, Takeda, and UCB. SC Taylor has received honoraria/stock options serving as an advisor/consultant and/or speaker for AbbVie, Arcutis, Aramis, Avita, Beiersdorf, Cara, Dior, Eli Lilly, EPI, Evolus, Galderma, Glotter, Hugel America, Johnson & Johnson, L'Oréal, Medscape/WebMD, MJ Life Sciences, Piction Health, Sanofi-Regeneron, Scientis US, UCB, and Vichy; has received honoraria/Board of Directors from Mercer Strategies; served as an author/received royalties from McGraw-Hill; served on the editorial board for Archives in Dermatologic Research, British Journal of Dermatology (peer review), Cuts, and Practical Dermatology, served as an investigator for Concert Pharmaceuticals, Cromapharma, Eli Lilly, and Pfizer.