

VISIBLE: Guselkumab Impact on Psoriatic Arthritis Through Week 100 in Participants With Moderate-to-Severe Psoriasis and Uncontrolled Psoriatic Arthritis Across All Skin Tones

Joseph F. Merola,¹ Richard G. Langley,^{2*} Maryam Shayesteh-Alam,³ Andrea Nguyen,⁴ Theodore Alkousakis,⁵ Sarah Ofori,⁵ Elizabeth Adamson,⁵ Tony Ma,⁵ Joe K. Tung,⁶ Alice B. Gottlieb¹

¹UT Southwestern Medical Center, Dallas, USA; ²Dalhousie University, Halifax, Canada; ³SimcoDerm Medical and Surgical Dermatology Centre, Barrie, Ontario, Canada; ⁴First OC Dermatology, Fountain Valley, CA, USA; ⁵Johnson & Johnson, Horsham and Spring House, PA, USA; ⁶University of Pittsburgh Medical Center, Pittsburgh, PA, USA

*Presenting author

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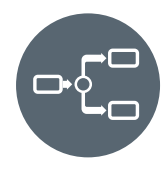
BACKGROUND



Psoriasis (PsO) remains frequently misdiagnosed and undertreated among individuals with skin of color (SoC).^{1,2}



Scalp PsO is a risk factor for development of psoriatic arthritis (PsA)



VISIBLE is a Phase 3b study that enrolled participants who self-identified as non-white and have moderate-to-severe plaque (Cohort A) or scalp (Cohort B) PsO



VISIBLE participants were evaluated for PsA at screening based on

- Rheumatologist-confirmed diagnosis of PsA
- Psoriasis Epidemiology Screening Tool (PEST) score ≥ 3

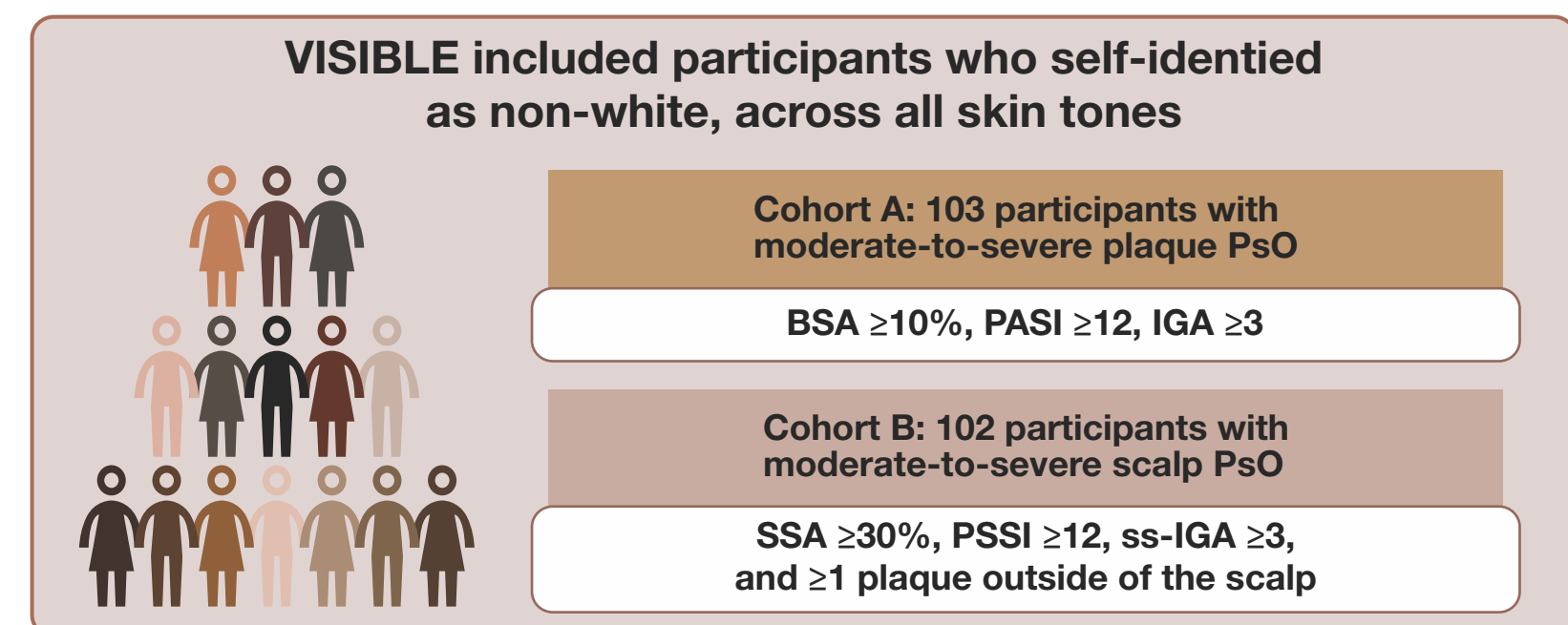


Participants were considered to have uncontrolled PsA at baseline if they had a 12-item Psoriatic Arthritis Impact of Disease questionnaire (PsAID-12) score of >4.0

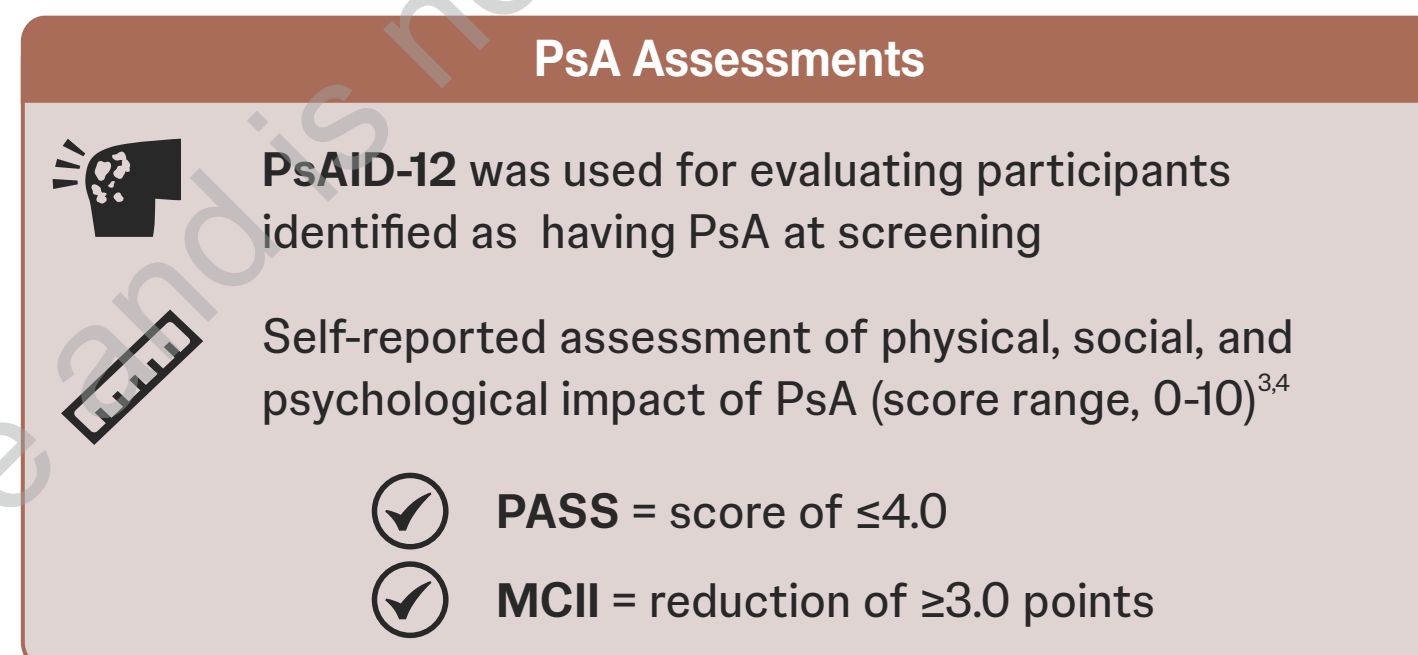
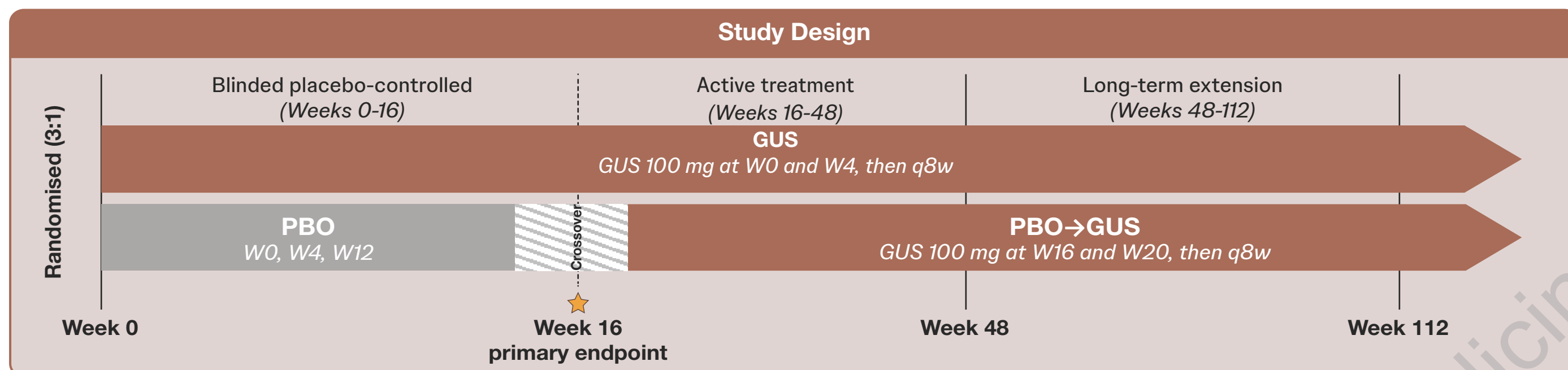
- The PsAID-12 patient-acceptable symptom state (PASS) is defined as a score of ≤ 4.0 ³

OBJECTIVES/METHODS

This post-hoc analysis reports PsAID-12 results through Week 100 for participants with uncontrolled PsA at baseline*



*Efficacy analysis set: VISIBLE Cohorts A and B, 22.9% (n=47) had uncontrolled PsA, PsAID ≥ 4 at baseline. BSA=body surface area, GUS=guselkumab, IGA=Investigator's Global Assessment, MCII=Minimal clinically important improvement, PASI=Psoriasis Area and Severity Index, PASS=Patient Acceptable Symptom Score, PBO=placebo, PsA=psoriatic arthritis, PSSI=Psoriasis Scalp Severity Index, q8w=every 8 weeks, SSA=Scalp surface area, ss-IGA=Scalp-specific IGA, W=week.



RESULTS

At baseline, 29.8% (61/205) of VISIBLE Cohort A and B participants had PsA (full efficacy analysis set). Of these, 47 participants had either a history of rheumatologist-diagnosed PsA (n=19 [40.4%]) or PEST ≥ 3 at screening (n=28 [59.6%]) with previously undiagnosed PsA) AND a PsAID-12 score >4.0 at baseline

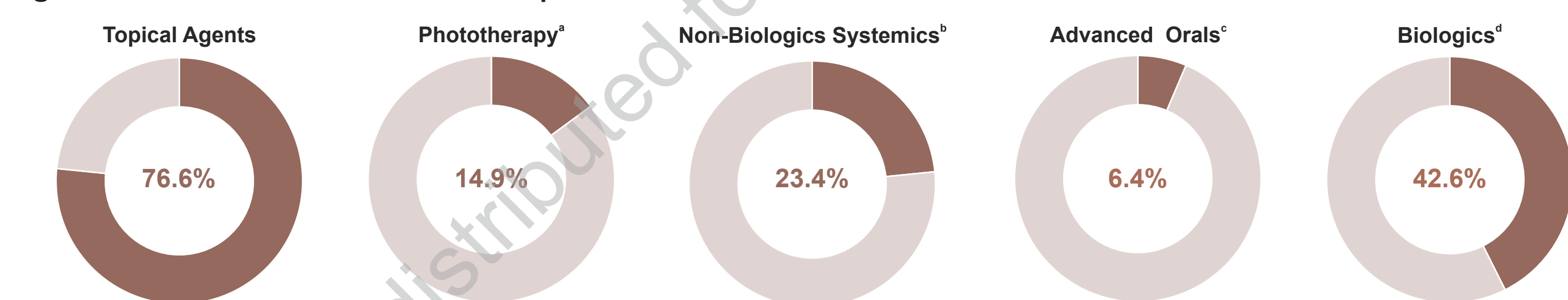
Baseline demographics and disease characteristics were generally comparable between PsA patients diagnosed by a rheumatologist and those with PsA identified by PEST screening (Table 1) and between GUS and PBO treatment groups (data not shown)

Table 1. Baseline Characteristics	Rheumatologist-Confirmed Diagnosis of PsA (N=19)	Screening PEST Score ≥ 3 (N=28)
Demographics		
Age, yrs	45.6 (13.5)	41.9 (12.5)
Male	63%	68%
Race		
Hispanic	32%	54%
Black	32%	7%
Asian	16%	29%
Middle Eastern	10%	4%
Multi-racial	10%	4%
Pacific Islander or Native Hawaiian	0%	4%
BMI, kg/m ²	32.7 (9.3)	34.8 (10.2)
Fitzpatrick skin type		
I-III	16%	14%
IV-VI	84%	86%
Disease Characteristics		
PsO disease duration, yrs	12.6 (10.5)	11.1 (8.3)
IGA, moderate (3)	74%	86%
BSA, %	23.4 (17.6)	23.8 (15.3)
PASI (0-72)	18.7 (9.4)	20.8 (8.1)
PSSI (0-72)	31.4 (19.0)	25.7 (13.2)
PsAID-12 score	7.0 (1.4)	7.9 (1.7)

Data shown are mean (SD), unless otherwise indicated. BMI=body mass index, BSA=body surface area, IGA=Investigator's Global Assessment, PASI=Psoriasis Area and Severity Index, PASS=Patient Acceptable Symptom Score, PBO=placebo, PsA=psoriatic arthritis, PsAID-12=12-item Psoriatic Arthritis Impact of Disease, PsO=psoriasis, PSSI=Psoriasis Scalp Severity Index, SD=standard deviation.

- Among the 47 participants with uncontrolled PsA at baseline, prior treatments included topicals (76.6%), phototherapy (14.9%), methotrexate (21.3%), apremilast (6.4%), and biologics (42.6%) any biologic; tumor necrosis factor 21.3%, interleukin (IL)-17 19.1%, and IL-12/23 inhibitors 19.1% (Figure 1)

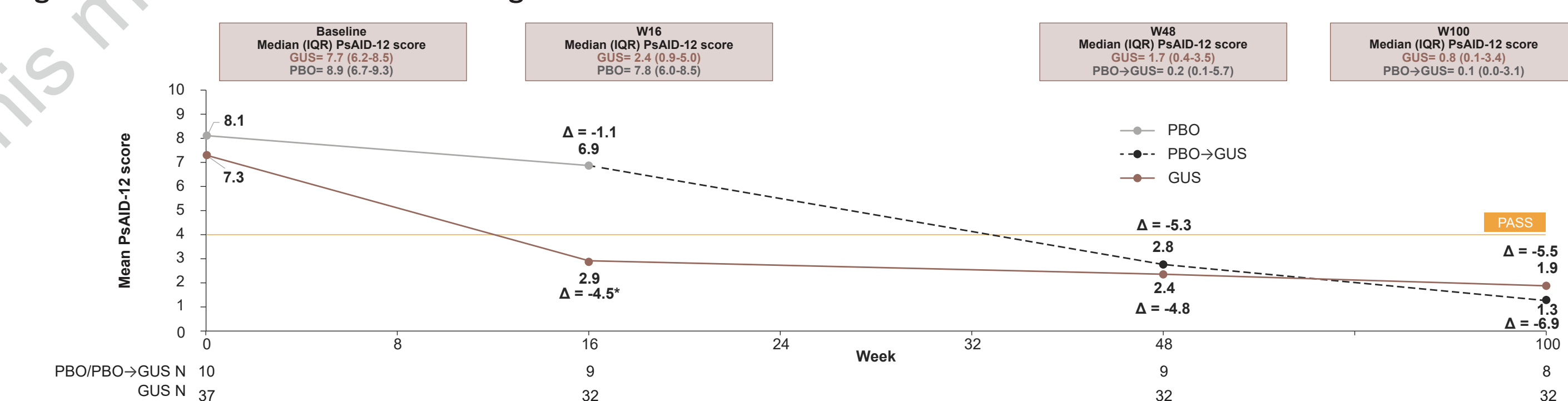
Figure 1. Previous PsO Medications/Therapies



*Includes PUVA or UVB. *Includes PUVA, methotrexate, cyclosporine, acitretin. *Includes apremilast. *Includes etanercept, infliximab, adalimumab, certolizumab, brodalumab, ixekizumab, secukinumab, ustekinumab. PsO=psoriasis, PUVA=Psoralen plus ultraviolet A, UVB=Ultraviolet B.

The GUS-randomized group with uncontrolled PsA at baseline had significantly decreased (improved) mean PsAID-12 score at Week 16 compared to the PBO-randomized group; mean PsAID-12 scores for the GUS and PBO→GUS subgroups continued to improve through Week 100 (Figure 2)

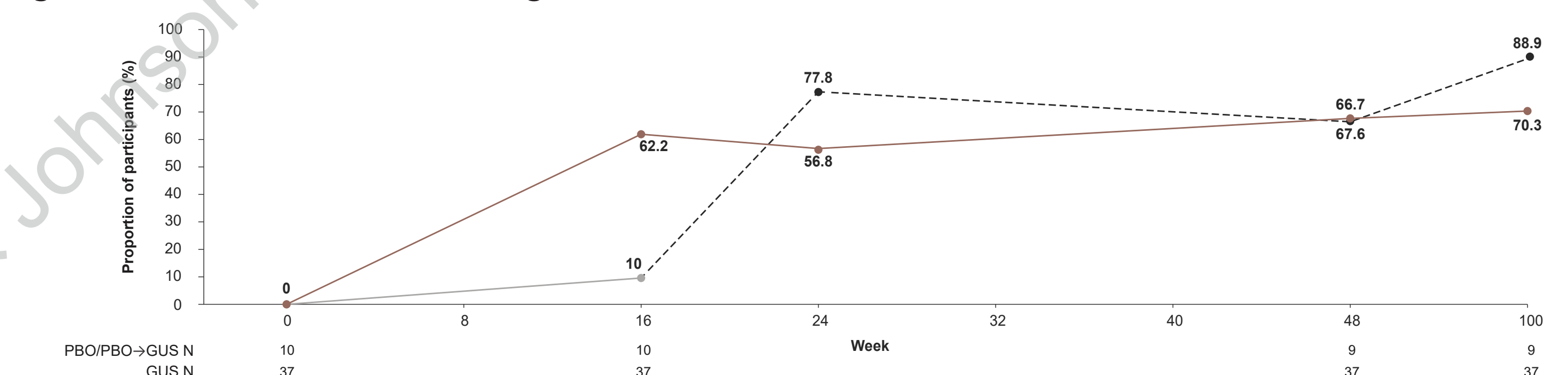
Figure 2. Mean PsAID-12 Scores Through Week 100*



*Efficacy analysis set included participants with uncontrolled PsA at baseline. After applying the intercurrent event (ICE) strategy, missing data were not explicitly imputed. *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-II or IV-VI) as covariates; all p-values are nominal as this is a post hoc analysis and also sample size is small in PBO group. Participants who met treatment failure rules (discontinued study agent due to lack of efficacy, had worsening PsO, or initiated a prohibited psoriasis treatment prior to Week 16) were assigned a change from baseline=0. Missing data were not imputed. FST=Fitzpatrick skin type, GUS=guselkumab, ICE=intercurrent event, IQR=inter quartile range, LS=least square, PBO=placebo, PsA=psoriatic arthritis, PsAID-12=12-item Psoriatic Arthritis Impact of Disease, PsO=psoriasis, W=week.

At Week 100, more than 70% of GUS-treated participants with uncontrolled PsA at baseline achieved PASS (PsAID-12 score ≤ 4.0 ; Figure 3)

Figure 3. Achievement of PASS Through Week 100*



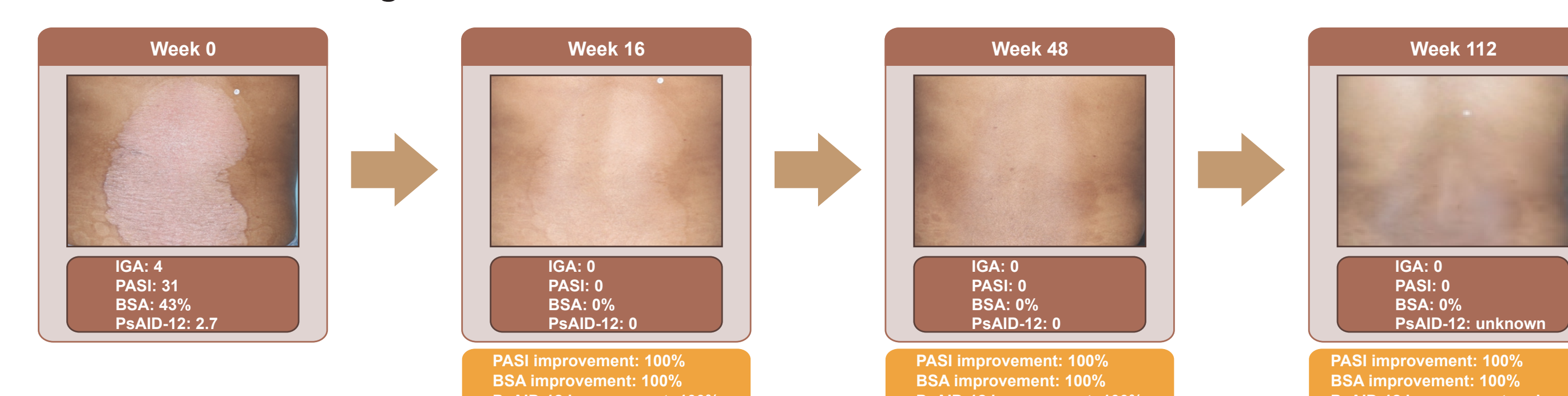
*Efficacy analysis set included participants with uncontrolled PsA at baseline. After applying the ICE strategy, missing data were not explicitly imputed. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included. GUS=guselkumab, ICE=intercurrent event, PASS=Patient Acceptable Symptom Score, PBO=placebo, PsA=psoriatic arthritis.

Figure 4. Participant Who Achieved IGA 0/1, PASI 90, and PsAID-12=0 at Week 16 and Maintained Responses Through Week 100



BSA=body surface area, IGA=Investigator's Global Assessment, PASI=Psoriasis Area and Severity Index, PsAID-12=12-item Psoriatic Arthritis Impact of Disease.

Figure 5. Participant Who Achieved IGA 0, PASI 100 (Complete Clearance), and PsAID-12=0 at Week 16 and Maintained Clear Skin Through Week 100



BSA=body surface area, IGA=Investigator's Global Assessment, PASI=Psoriasis Area and Severity Index, PsAID-12=12-item Psoriatic Arthritis Impact of Disease.

CONCLUSIONS

At baseline, approximately one quarter of VISIBLE participants had uncontrolled PsA (based on having a PsAID-12 score above the PASS threshold of 4.0), indicating lack of awareness of the need for routine PsA screening by dermatologists, including patients across all skin tones

Specifically, PsA screening with the PEST in patients with PsO, especially those with risk factors, should be considered to enable early detection, initiation of appropriate treatment, and improved outcomes in PsA

In participants with uncontrolled and often undiagnosed PsA at baseline, treatment with GUS provided clinically meaningful improvements in the physical and psychological impact of joint disease, based on mean PsAID-12 scores decreasing below the PASS at Week 16

Improvements in PsAID-12 scores continued and were maintained through 100 weeks of GUS treatment