

VISIBLE COHORT A: GUSELKUMAB SKIN CLEARANCE AND PATIENT-REPORTED OUTCOMES ACROSS SKIN AND JOINT SYMPTOMS THROUGH WEEK 100 IN PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS ACROSS ALL SKIN TONES

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This presentation was supported by Johnson & Johnson, Horsham, PA, USA.



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OBJECTIVE/METHODS

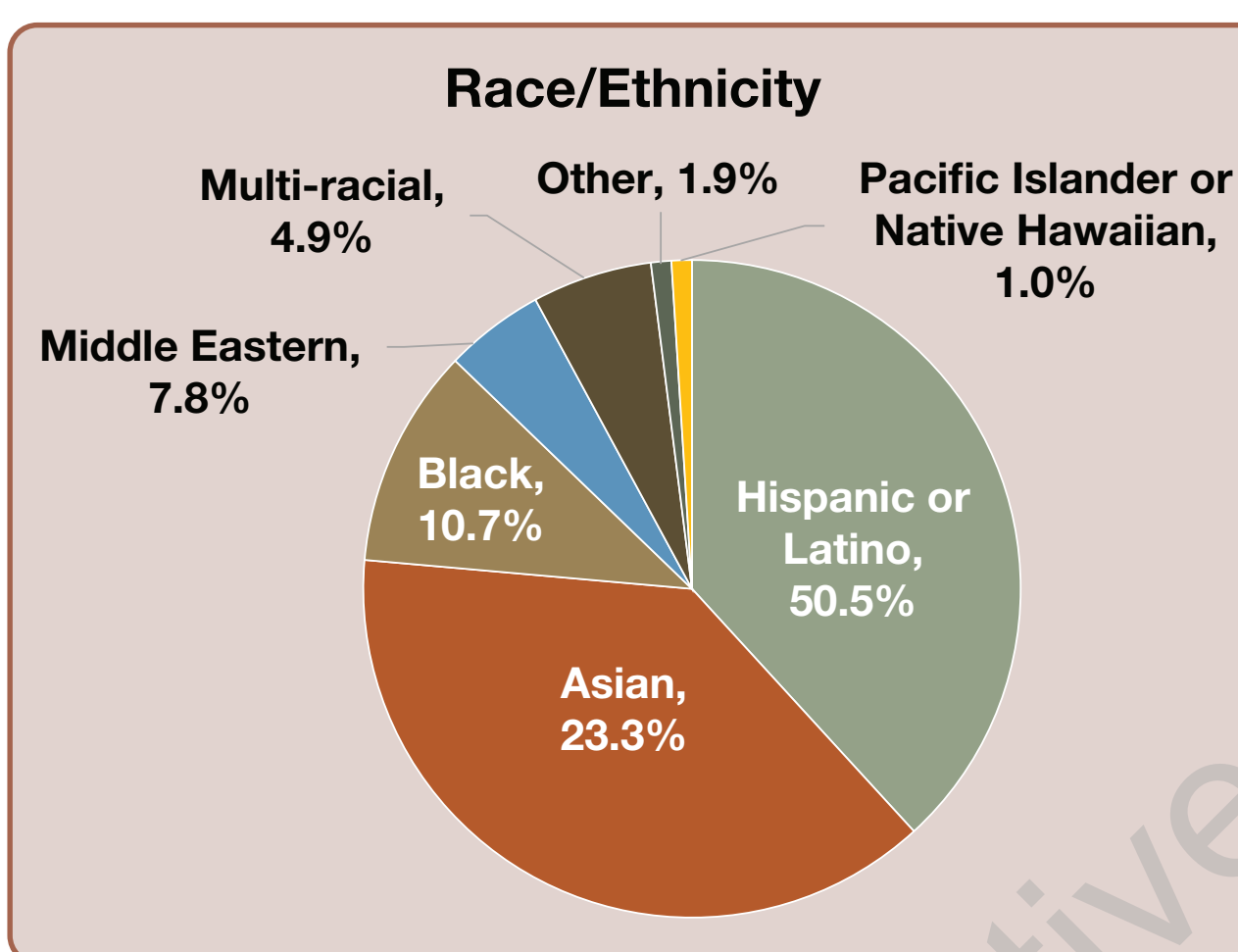
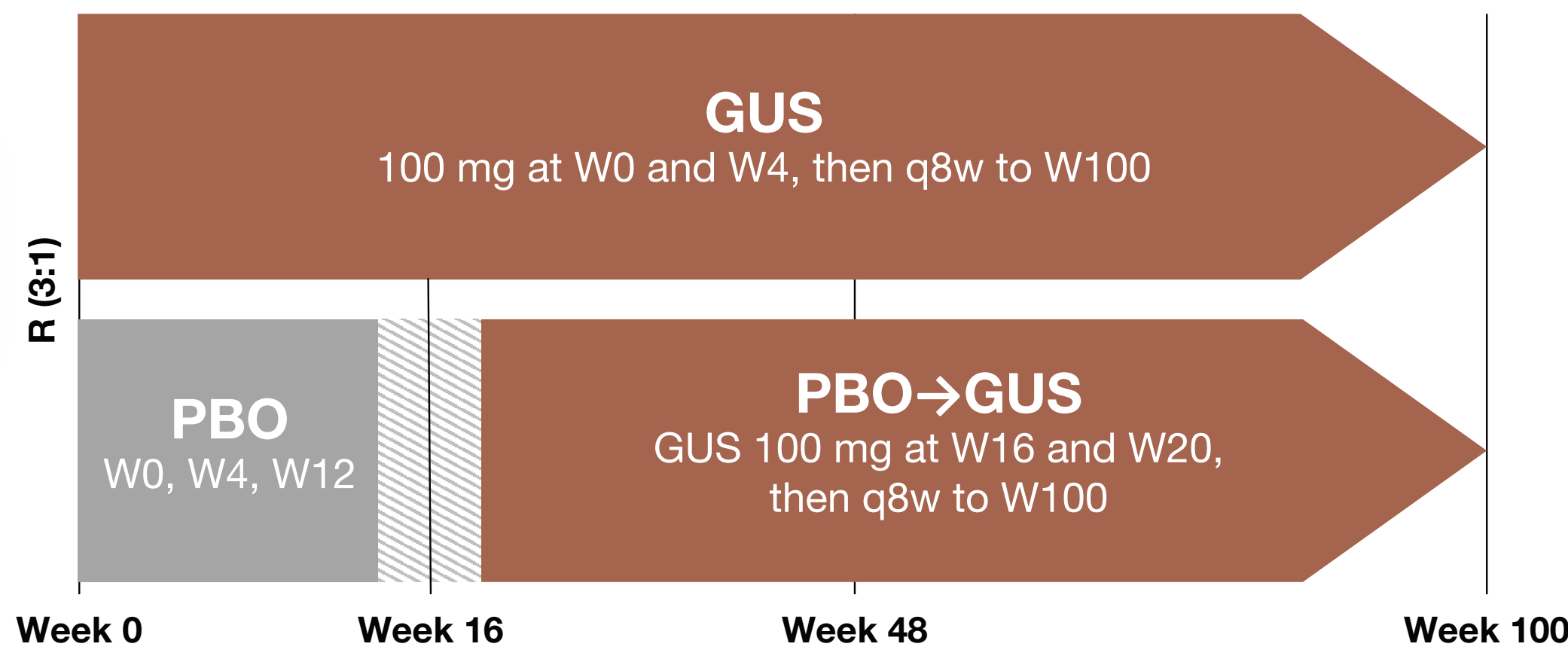
Evaluate efficacy, safety, and impact of GUS treatment on patient-reported PsO symptoms and HRQoL in Cohort A through 2 years

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

VISIBLE Study Design

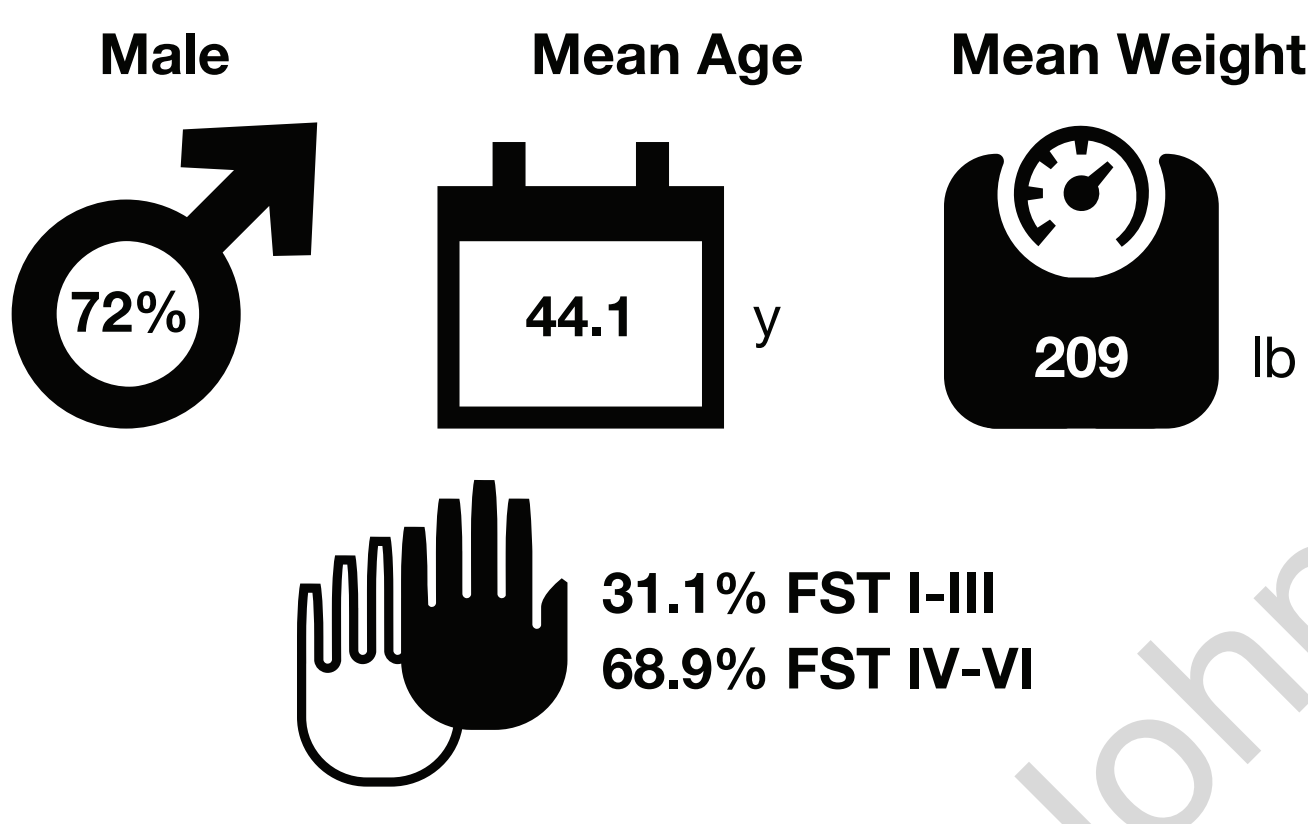
Cohort A: 103 participants with moderate-to-severe plaque PsO BSA $\geq 10\%$, PASI ≥ 12 , IGA ≥ 3

Cohort B: 108 participants with moderate-to-severe scalp PsO SSA $\geq 30\%$, PSSI ≥ 12 , ss-IGA ≥ 3 , ≥ 1 plaque outside of the scalp



Cohort A Baseline Disease Characteristics*		
	PBO (N=26)	GUS (N=77)
PsO Duration, y	14.9 (8.8)	14.9 (11.0)
IGA, n (%)		
Moderate 3	21 (80.8)	57 (74.0)
Severe 4	5 (19.2)	20 (26.0)
PSSI (0-72)	19.8 (6.2)	21.2 (9.9)
BSA, %	26.1 (15.9)	27.0 (20.4)

Cohort A Demographics (N=103)



*Mean (SD) unless otherwise noted. **BSA**=Body surface area; **FST**=Fitzpatrick skin type; **GUS**=Guselkumab; **HRQoL**=Health-related quality of life; **lb**=pound; **IGA**=Investigator's Global Assessment; **PASI**=Psoriasis Area and Severity Index; **PBO**=Placebo; **PsO**=Psoriasis; **PSSI**=Psoriasis Scalp Severity Index; **q8w**=Every 8 weeks; **R**=Randomized; **SD**=Standard deviation; **SSA**=Scalp surface area; **ss-IGA**=Scalp-specific-Investigator's Global Assessment; **W**=Week; **y**=Year.

RESULTS

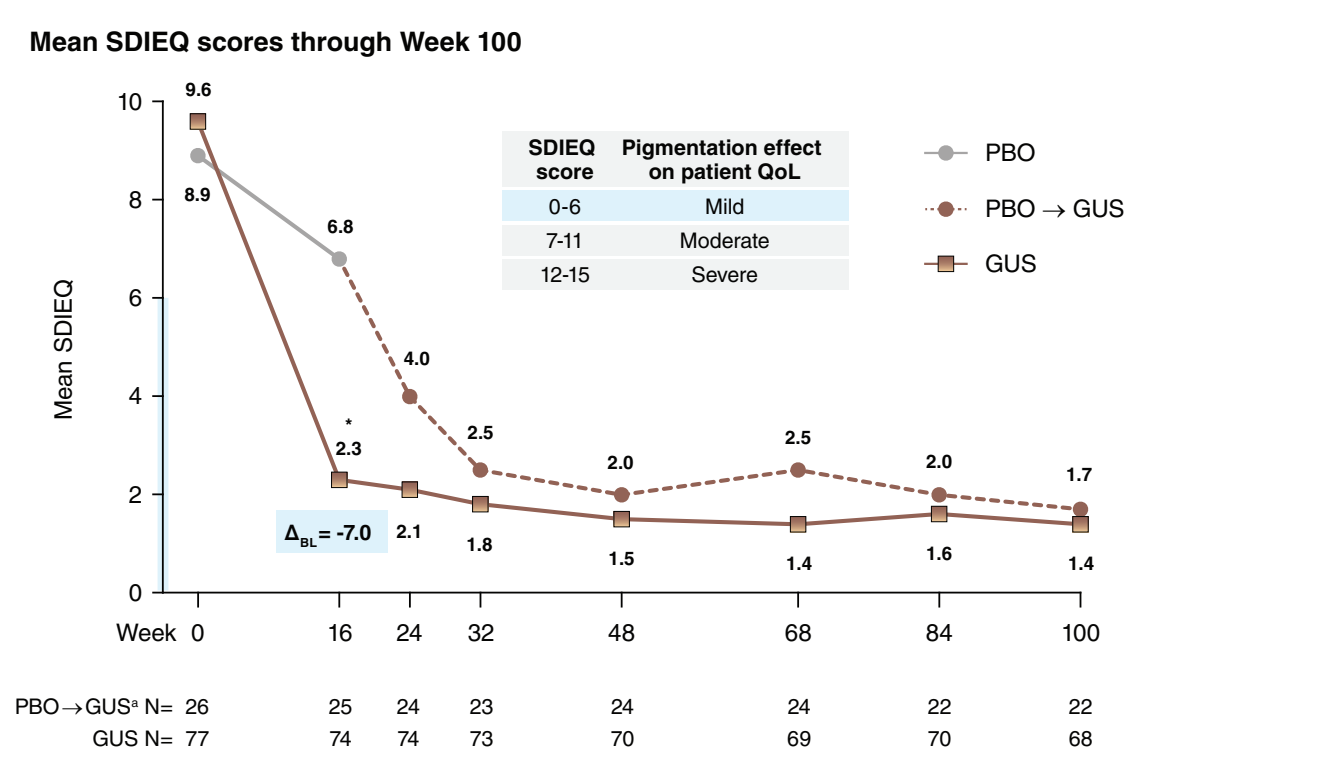
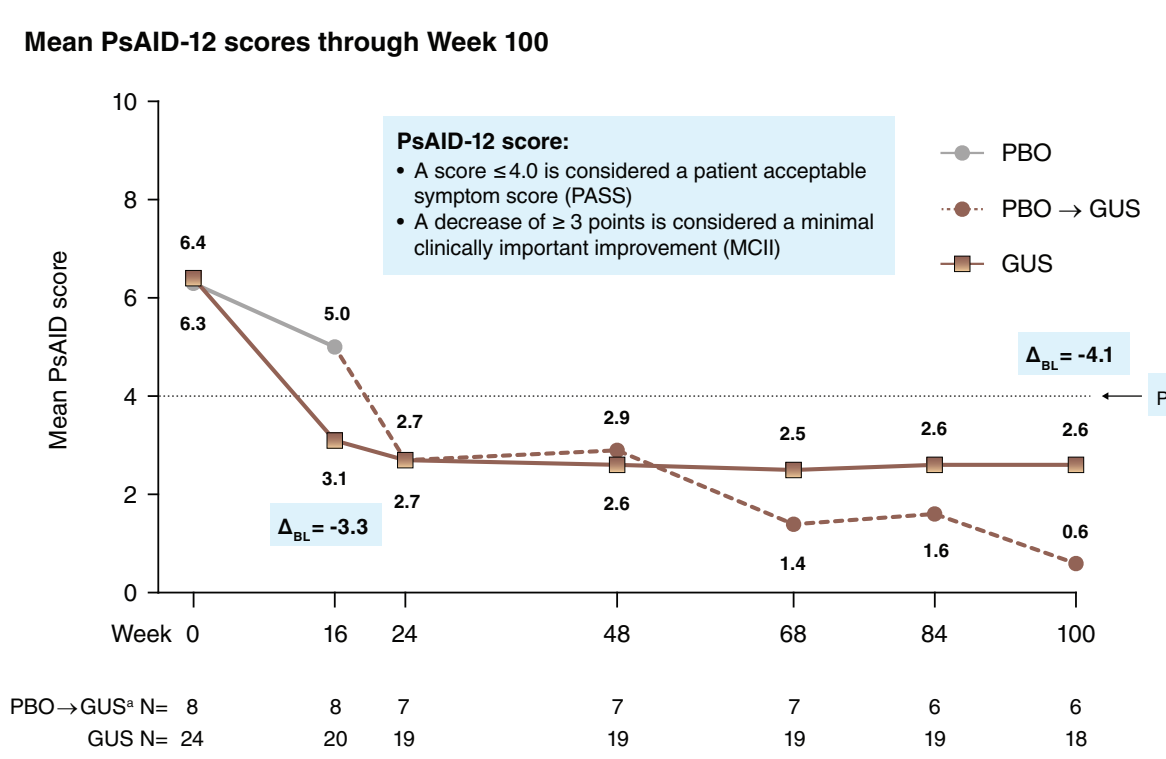
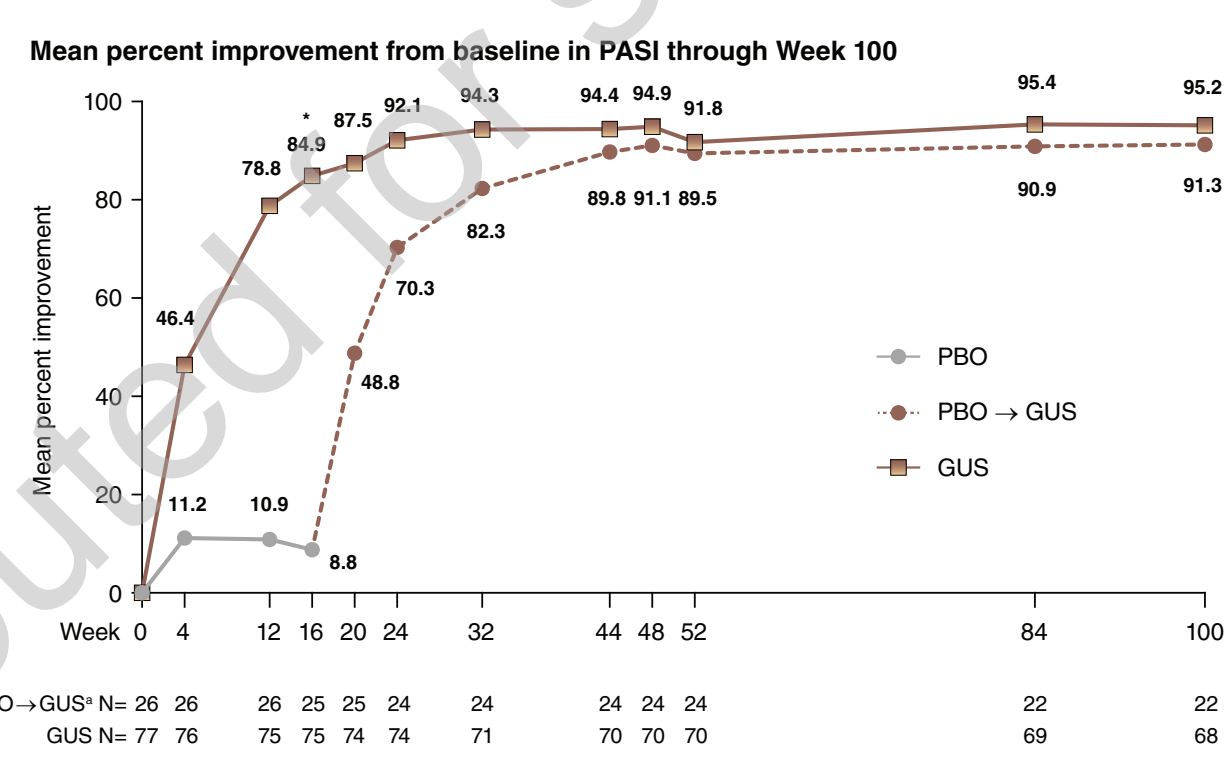
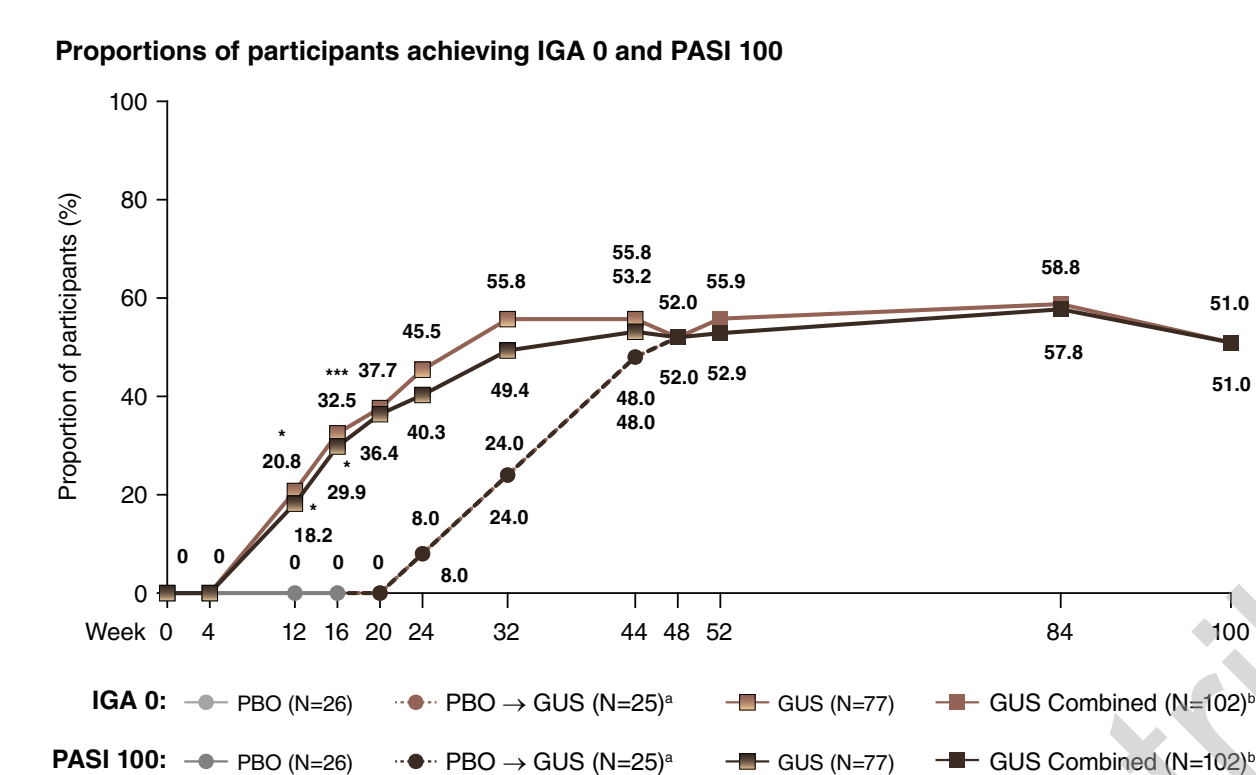
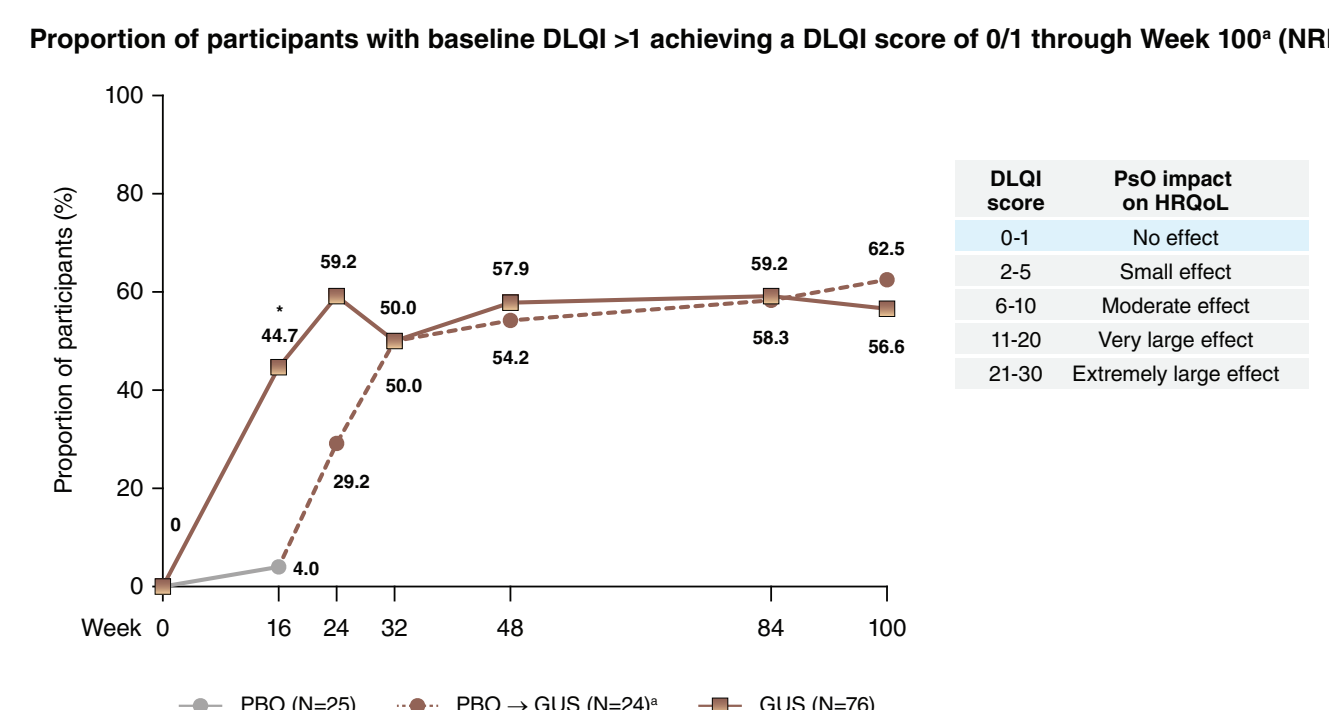
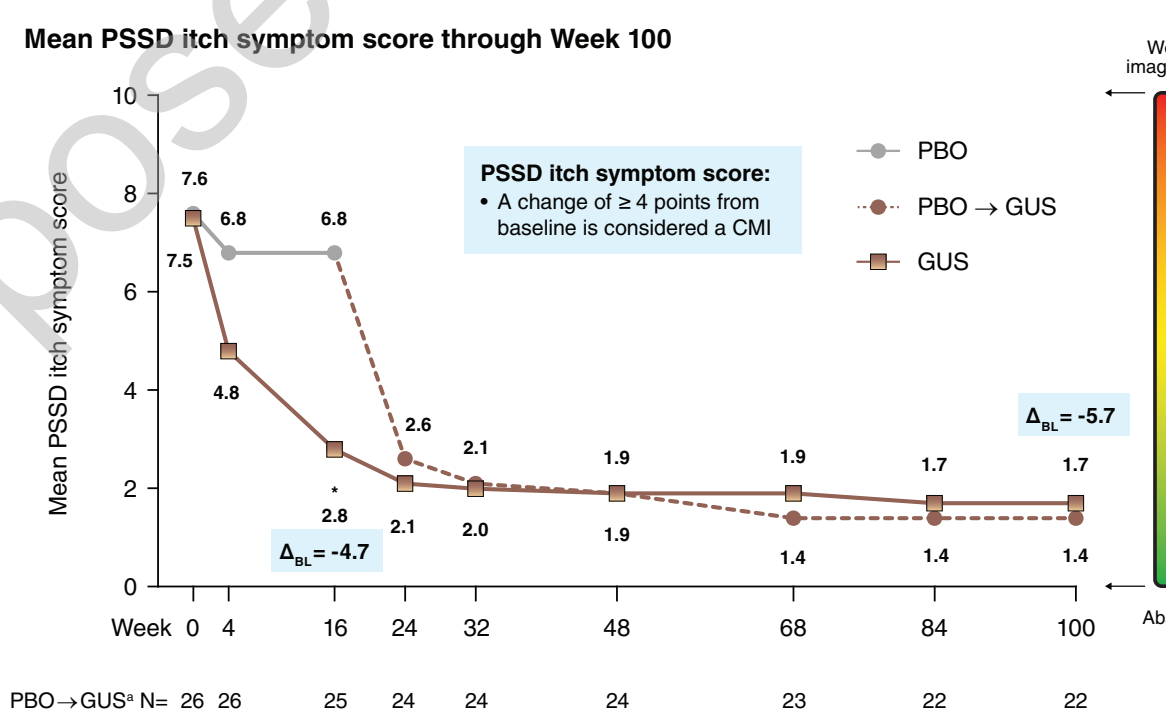
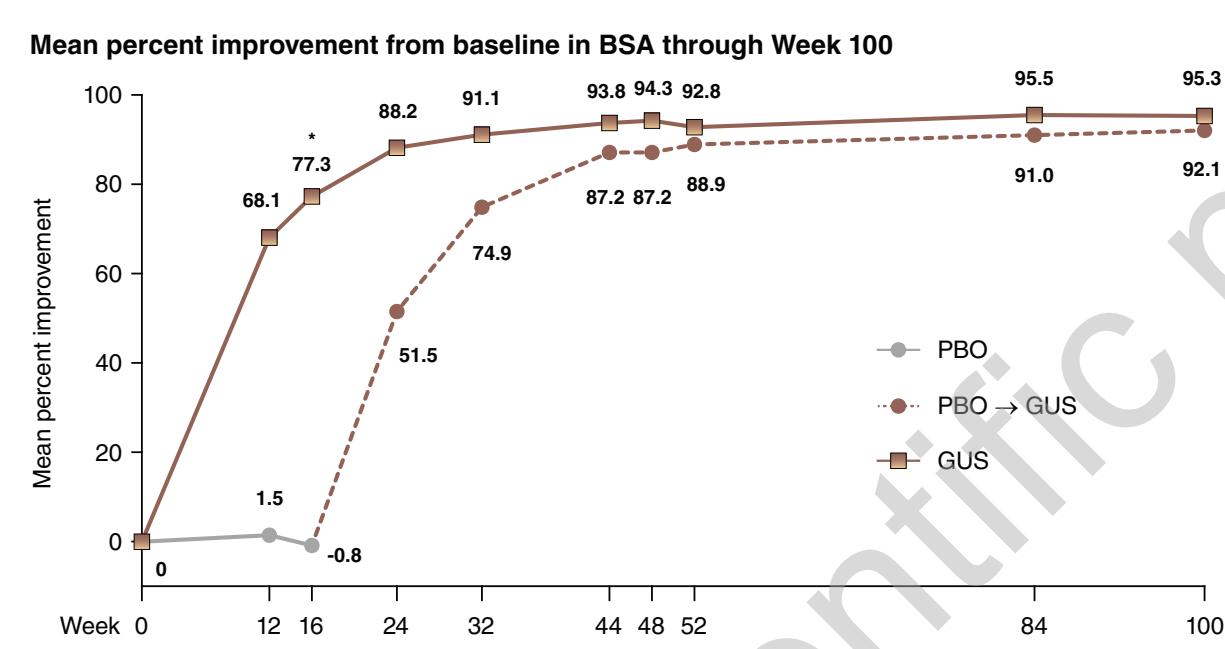
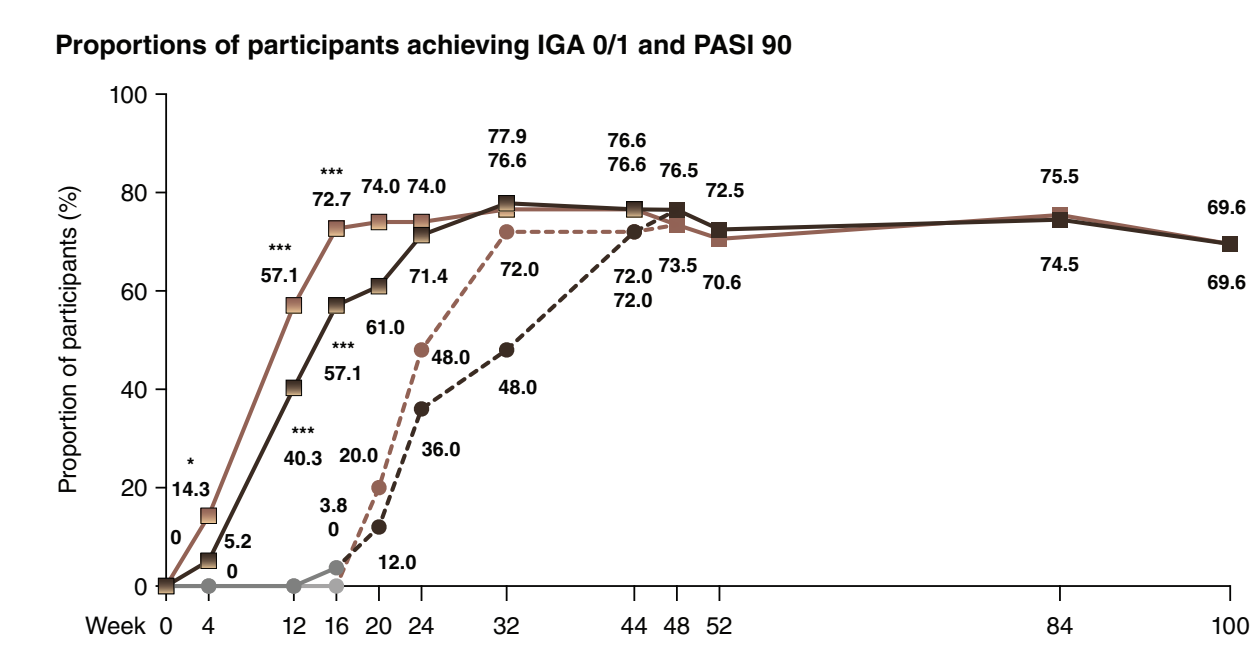
- Significantly greater IGA 0/1, IGA 0, PASI 90, and PASI 100 response rates were achieved in the GUS-randomized vs PBO group at Week 16. Response rates were generally sustained or improved through Week 100 for both the GUS and PBO→GUS groups (non-responder imputation [NRI]).
- Mean percent improvements in BSA and PASI increased over time and were maintained at >90% with continued GUS treatment through Week 100

- GUS treatment provided significantly greater improvements in patient-reported outcomes (PSSD itch, PsAID-12, SDIEQ, and DLQI) vs PBO at Week 16. Improvements were sustained/improved for the GUS-randomized and PBO→GUS groups through Week 100.

GUS-Treated Participant Who Achieved IGA 0 and PASI 100 (Complete Skin Clearance) at Week 16



- Following GUS treatment, no new safety signals were observed through Week 112



*p<0.05 vs PBO; ***p<0.001 vs PBO; p-values were based on the Cochran-Mantel-Haenszel (CMH) test stratified by FST (I-III/IV-VI). *For participants who were randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included in Weeks 20-100. *Includes participants randomized to GUS at baseline and participants randomized to PBO at baseline who then crossed over to receive GUS at or after Week 16. 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. **BSA**=Body surface area; **FST**=Fitzpatrick skin type; **GUS**=Guselkumab; **IGA**=Investigator's global assessment; **PASI**=Psoriasis area and severity index; **PBO**=Placebo; **PsO**=Psoriasis.

*nominal p<0.001 vs PBO; p-values for Mean PSSD Itch Symptom Score based on mixed model for repeated measures; explanatory variables included treatment group, visit, baseline score, FST (I-III/IV-VI), interaction term of visit with treatment group, and interaction term of visit with baseline score. p-value for Mean SDIEQ Scores based on ANCOVA model. The explanatory variables of the ANCOVA model included treatment group, baseline score, and Fitzpatrick Type (Type I-III/Type IV-VI). aFor participants who were randomized to PBO at W0, only those who crossed over to GUS at or after W16 were included. Zero change from baseline was assigned if participants discontinued due to lack of efficacy or worsening PsO or used a prohibited PsO treatment (intercurrent events). Δ BL=Mean change from baseline; p-value for proportion of subjects with DLQI=0/1 based on the CMH test stratified by FST (Type I-III/Type IV-VI). **ANCOVA**=Analysis of covariance; **CMH**=Cochran-Mantel-Haenszel; **CMH**=Clinically meaningful improvement; **DLQI**=Dermatology Life Quality Index; **FST**=Fitzpatrick skin type; **PsAID-12**=Psoriasis Arthritis Impact of Disease-12 Questionnaire; **PsO**=Psoriasis; **PSSD**=Psoriasis Symptoms and Signs Diary; **SDIEQ**=Skin Discoloration Impact Evaluation Questionnaire; **W**=Week.

	PBO (W0-16) N=26	GUS (W0-16) N=77	PBO→GUS* (W16-112) N=25	GUS (W0-112) N=77
Key Safety Information				
Mean weeks of follow-up	16.0	16.1	91.5	104.4
Participants with ≥ 1 AE	5 (19.2)	29 (37.7)	13 (52.0)	58 (75.3)
AEs leading to discontinuation of study agent ^a	0	1 (1.3)	0	2 (2.6)
Serious AEs ^a	0	0	1 (4.0)	3 (3.9)
AEs of interest				
Infections	3 (11.5)	16 (20.8)	7 (28.0)	38 (49.4)*
Serious infections	0	0	1 (4.0)	3 (3.9)
Clinically important hepatic disorders ^a	0	0	0	0
Major adverse cardiovascular events	0	0	0	0
Malignancy	0	0	0	0
Venous thromboembolism	0	0	0	0
Serum-like sickness or anaphylaxis	0	0	0	0
Tuberculosis	0	0	0	0
Inflammatory bowel disease	0	0	0	0
Data shown are n (%), unless otherwise indicated.				

*For participants randomized to PBO at Week 0, only those who crossed over to GUS at or after Week 16 were included. *Weeks 0-16: 1 GUS participant discontinued due to impetiginized atopic dermatitis; Weeks 0-112: Includes 1 GUS participant who discontinued due to pregnancy and the 1 GUS participant with impetiginized atopic dermatitis who discontinued at Weeks 0-16. *Weeks 16-112: 1 PBO→GUS participant had localized hand/wrist cellulitis; Weeks 0-112: 1 GUS participant had a gallbladder abscess and bile duct perforation, 1 had appendicitis, and 1 had cyclonephritis. *Infections reported in >1 GUS-randomized participant included upper respiratory tract infections (16.9%), nasopharyngitis (11.7%), COVID-19 (6.5%), herpes simplex (2.6%), pharyngitis (2.6%), urinary tract infection (2.6%), and viral upper respiratory tract infection (2.6%). *No clinically important hepatic disorder events based on a narrow Hepatic Disorders Standardised MedDRA Queries search and recorded as serious or leading to treatment discontinuation. **AE**=Adverse event; **BSA**=Body surface area; **GUS**=Guselkumab; **IGA**=Investigator's global assessment; **MedDRA**=Medical Dictionary for Regulatory Activities; **PASI**=Psoriasis area and severity index; **PBO**=Placebo; **W**=Week.