

# SPECTREM: Guselkumab Patient-Reported Outcomes Across Multiple High-Impact Sites in Participants With Low BSA, Moderate Psoriasis: Psoriasis Symptoms and Signs Diary Deep Dive

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## Background

Patients with psoriasis (PsO) affecting the scalp, face, intertriginous areas, and/or genital region experience disproportionately high levels of physical impairment and emotional distress,<sup>1-3</sup> even when a low percentage of the overall body surface area (BSA) is involved<sup>3</sup>

SPECTREM is a recently completed Phase 3b, randomized, double-blind, placebo (PBO)-controlled study that evaluated guselkumab (GUS) efficacy and safety in participants with low BSA (2–15%), moderate plaque PsO (Investigator’s Global Assessment [IGA]=3) involving ≥1 high-impact site (scalp, face, intertriginous, genitals), and who had failed at least one topical therapy<sup>4</sup>

## Objective

This analysis describes changes from baseline in Psoriasis Symptoms and Signs Diary (PSSD) measures by site-specific subgroups at Week 16 and through Week 48 for participants with baseline:

- Scalp-specific IGA (ss-IGA≥3)
- Facial IGA (f-IGA≥3)
- Intertriginous IGA (i-IGA≥3)
- Static PGA of Genitalia (sPGA-G≥3)

## Methods

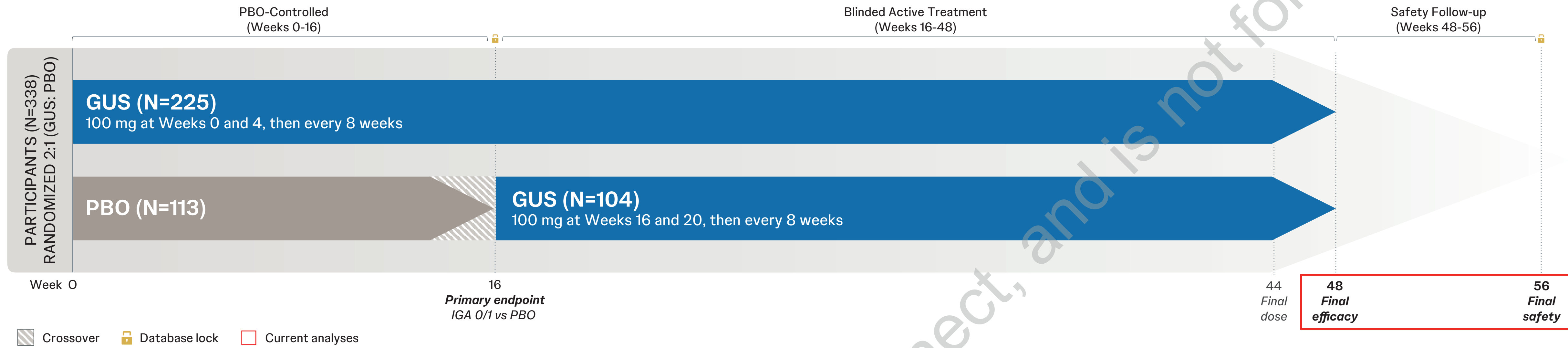
### Key inclusion criteria

- IGA=3
- BSA=2-15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact site (scalp, face, intertriginous, genital) with at least moderate severity (site-specific IGA/PGA ≥3)
- Inadequately controlled with or intolerant to ≥1 prior topical therapy

- At baseline, Week 16, and Week 48, participants used the PSSD to rate symptoms (itch, pain, stinging, burning, skin tightness) and signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) in the past 7 days, on a scale from 0 to 10

- PSSD scores were defined as 0=absent, >0 to <4=mild, 4 to <7=moderate, and 7-10=severe (10=worst imaginable)

- Clinically meaningful improvement (CMI) was defined as an improvement from baseline of ≥3 points for bleeding and stinging; ≥4 points for itch, dryness, cracking, skin tightness, burning, and pain; and ≥5 points for scaling, shedding or flaking, and redness<sup>5</sup>



## Results

Baseline PSSD scores were generally balanced across all high-impact sites (scalp, face, intertriginous, genital) and between the PBO→GUS and GUS groups

Table 1. Baseline PSSD scores by high-impact site and severity

Item (CMI threshold)	Scalp ss-IGA ≥3		Face f-IGA ≥3		Intertriginous i-IGA ≥3		Genital sPGA-G ≥3	
	PBO→GUS N=76	GUS N=152	PBO→GUS N=41	GUS N=90	PBO→GUS N=52	GUS N=111	PBO→GUS N=40	GUS N=82
Dryness (≥4)	7.7	7.4	7.4	7.4	7.2	7.3	7.6	7.2
Shedding/flaking (≥5)	7.7	7.3	7.7	7.4	7.0	7.1	7.3	7.1
Redness (≥5)	7.2	7.0	7.0	7.2	7.2	7.0	7.4	7.3
Scaling (≥5)	7.8	7.3	7.3	7.3	7.2	7.0	7.6	6.9
Itch (≥4)	7.1	6.8	7.0	6.5	6.5	6.8	6.6	7.0
Cracking (≥4)	6.2	6.1	6.3	6.5	6.2	6.0	6.6	6.2
Skin tightness (≥4)	6.2	5.9	6.2	6.2	5.7	5.8	6.2	6.0
Stinging (≥3)	4.9	4.5	5.3	4.7	4.6	4.3	5.1	4.7
Burning (≥4)	4.9	4.7	4.8	5.0	4.8	4.6	5.2	5.2
Pain (≥4)	4.7	4.8	4.7	5.1	4.6	4.8	4.8	5.2
Bleeding (≥3)	3.4	3.7	4.0	3.6	3.4	3.5	3.6	4.0

PSSD baseline score severity key: Red = severe; Blue = moderate; Green = mild.

Least square mean improvements in PSSD scores from baseline to Week 16 were significantly higher for GUS vs PBO for all PSSD domains; CMI was achieved for 8 of 11 domains

Table 2. Least square mean improvements in PSSD scores from baseline to Week 16 by high-impact site and treatment group at Week 16†

Item (CMI threshold)	Scalp ss-IGA ≥3		Face f-IGA ≥3		Intertriginous i-IGA ≥3		Genital sPGA-G ≥3	
	PBO→GUS N=71	GUS N=147	PBO→GUS N=39	GUS N=88	PBO→GUS N=51	GUS N=109	PBO→GUS N=37	GUS N=79
Dryness (≥4)	-0.53*	-4.57*	-0.31	-4.68*	-0.81	-4.87*	-0.90	-4.93*
Shedding/flaking (≥5)	-0.57	-5.18*	-0.42	-5.25*	-0.72	-5.22*	-1.11	-5.34*
Redness (≥5)	-0.56	-4.69*	-0.63	-5.05*	-1.15	-5.06*	-1.13	-5.03*
Scaling (≥5)	-0.59	-5.28*	-0.20	-5.12*	-0.85	-5.23*	-1.12	-5.23*
Itch (≥4)	-0.19	-4.07*	0.36	-3.82*	-0.59	-4.33*	-0.82	-4.42*
Cracking (≥4)	-0.39	-4.20*	-0.28	-4.55*	-0.54	-4.48*	-0.82	-4.61*
Skin tightness (≥4)	-0.28	-3.85*	-0.29	-4.27*	-0.29	-4.09*	-0.83	-4.24*
Stinging (≥3)	0.38	-3.19*	0.54	-3.56*	0.10	-3.03*	-0.11	-3.48*
Burning (≥4)	0.08	-3.23*	0.05	-3.59*	-0.05	-3.31*	-0.62	-3.93*
Pain (≥4)	-0.08	-3.46*	-0.07	-3.70*	-0.18	-3.44*	-0.63	-3.99*
Bleeding (≥3)	0.39	-2.68*	0.46	-2.73*	0.26	-2.48*	-0.25	-2.91*

Green highlights indicates achievement of CMI.

\*Negative change indicates an improvement, and a positive change indicates worsening.

†For each high-impact site and PSSD item, p<0.001 for comparisons of GUS vs PBO→GUS. The least square means difference and the p-value were based on MMRM.

CMIs were achieved at Week 48 for the PSSD domains that were most severe at baseline

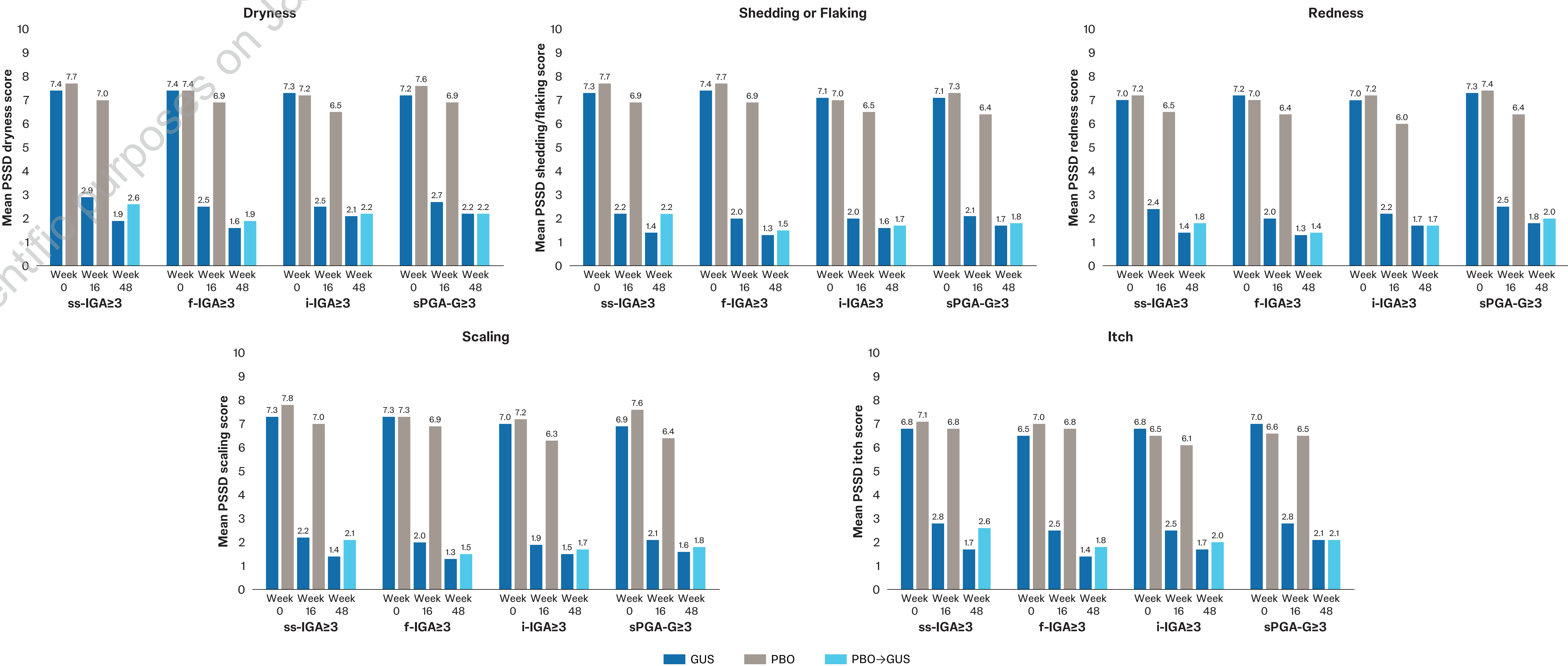
Table 3. Mean improvements in PSSD scores by high-impact site and treatment group at Week 48

Item (CMI threshold)	Scalp ss-IGA ≥3		Face f-IGA ≥3		Intertriginous i-IGA ≥3		Genital sPGA-G ≥3	
	PBO→GUS N=65	GUS N=141	PBO→GUS N=36	GUS N=83	PBO→GUS N=47	GUS N=107	PBO→GUS N=33	GUS N=75
Dryness (≥4)	-5.1	-5.5	-5.4	-5.8	-4.9	-5.2	-5.3	-5.0
Shedding/flaking (≥5)	-5.5	-5.9	-6.1	-6.0	-5.3	-5.6	-5.5	-5.4
Redness (≥5)	-5.3	-5.6	-5.6	-5.9	-5.6	-5.4	-5.4	-5.5
Scaling (≥5)	-5.6	-5.9	-5.7	-6.0	-5.4	-5.5	-5.7	-5.3
Itch (≥4)	-4.4	-5.1	-5.0	-5.1	-4.4	-5.1	-4.5	-4.9
Cracking (≥4)	-4.2	-4.9	-4.8	-5.4	-4.7	-4.7	-4.9	-4.8
Skin tightness (≥4)	-4.3	-4.5	-4.7	-5.2	-4.4	-4.3	-4.8	-4.3
Stinging (≥3)	-3.6	-3.5	-4.4	-3.8	-3.6	-3.3	-3.8	-3.2
Burning (≥4)	-3.6	-3.8	-4.1	-4.3	-3.8	-3.7	-3.9	-3.9
Pain (≥4)	-3.4	-3.9	-3.9	-4.2	-3.6	-3.8	-3.5	-3.9
Bleeding (≥3)	-2.4	-3.1	-3.4	-3.1	-2.7	-2.8	-3.1	-2.8

Green highlights indicates achievement of CMI.

\*For burning, pain, and bleeding items, mean baseline scores were in the mild to moderate range; thus, for many participants baseline scores were too low to achieve CMI.

Mean PSSD dryness, shedding/flaking, redness, scaling, and itch scores were the most severe domain scores at baseline across all high-impact sites. All mean scores decreased to the mild range at Week 16 with GUS and improved further through Week 48



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