

SPECTREM: Skin Clearance Results Through Week 48 With Guselkumab in Participants With Low Body Surface Area, Moderate Plaque Psoriasis and Palmoplantar Involvement

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Background

Historically, clinical trials evaluating use of systemic therapies for plaque psoriasis (PsO) require body surface area (BSA) involvement of ≥10%; however, the majority (>85%) of real-world patients with PsO have disease affecting ≤10% BSA,² and most have involvement of high-impact sites (eg, scalp, face, genitals, hands, and feet)³

- Palmoplantar PsO occurs in 12-16% of patients with PsO⁴ and is associated with significant burdens, including pain, and difficulty walking and using their hands⁵

The International Psoriasis Council expanded the criteria for systemic therapy eligibility by including patients with disease involving high-impact sites and patients who experienced failure of topical therapy,⁵ addressing potential undertreatment in these populations⁶

SPECTREM is a phase 3b, randomized, placebo (PBO)-controlled study that evaluated the efficacy and safety of guselkumab (GUS) in participants with low BSA, moderate plaque PsO involving ≥1 high-impact site who had failed ≥1 topical therapy⁷

- Significant improvements in skin clearance with GUS at Week 16⁷ and through Week 48⁸ were previously reported; GUS was well tolerated with no new safety signals^{7,8}

Objective

This post hoc analysis reports efficacy of GUS through Week 48 among participants with palmoplantar involvement at baseline using:

- Investigator's Global Assessment (IGA)
- Psoriasis Area and Severity Index (PASI)
- Palmoplantar-IGA (pp-IGA)
- BSA involvement

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/Physician Global Assessment [PGA] ≥3)
- Inadequately controlled with or intolerant of ≥1 prior topical therapy

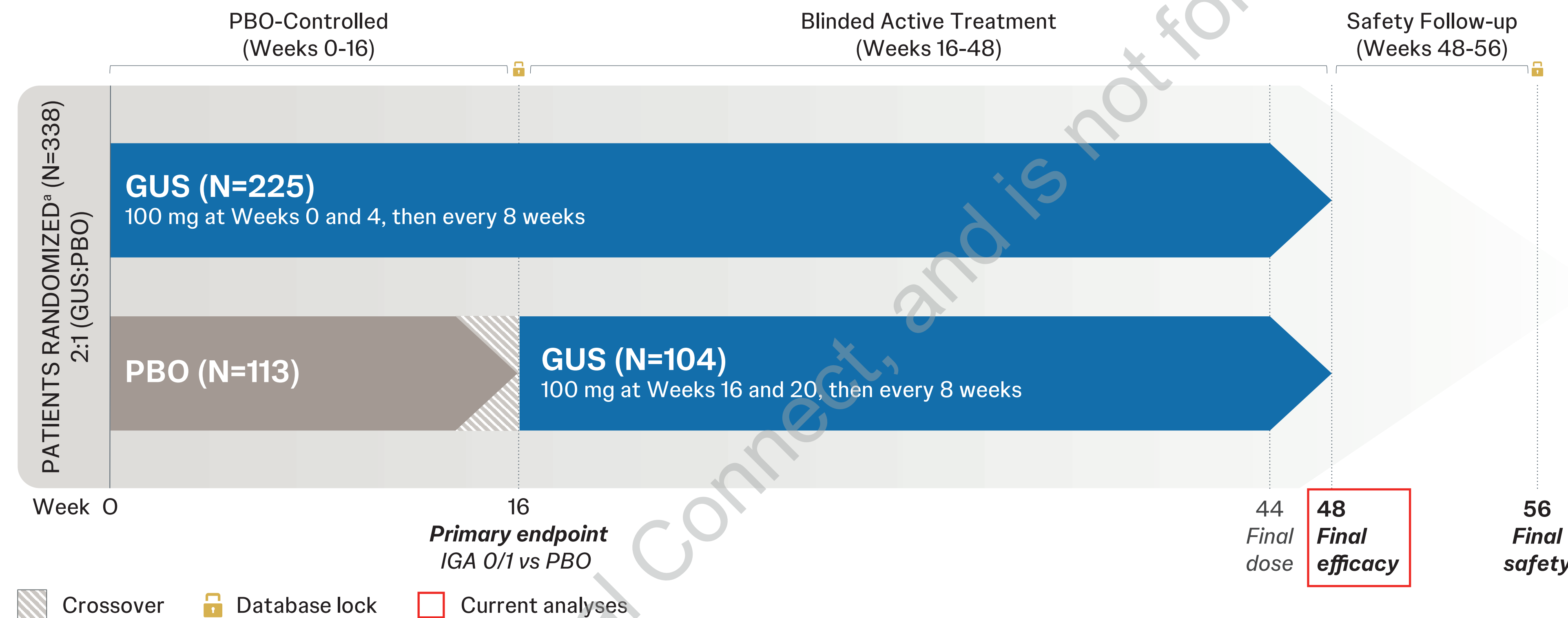
Current analysis

- Participants with pp-IGA >0: 8.9% (30/338)

Overall skin clearance through Week 48 was evaluated by:

- IGA 0/1 (cleared/minimal)
- IGA 0 (cleared)
- PASI 90 (≥90% improvement from baseline)
- PASI 100 (100% improvement from baseline)
- pp-IGA 0 (clear)
- Mean percent change in BSA involvement
- Mean percent change in PASI

*Randomization was stratified by high-impact site (scalp, face, intertriginous, genital). If participants had >1 qualifying high-impact site at baseline, they were allocated to the site that was most severe, as determined by the participant.



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Conclusions

Among participants with low BSA, moderate PsO and palmoplantar involvement, GUS provided robust rates of clear/almost clear skin by Week 16 that were sustained or increased through Week 48

Efficacy results were similar to those in the full SPECTREM population,^{8,9} with the limitation of a small palmoplantar cohort

Results

Baseline demographics and disease characteristics among participants with palmoplantar PsO were generally balanced between the PBO and GUS groups

| Baseline Characteristics | PBO (N=12) | GUS (N=18) | Total (N=30) |
|--|-------------|-------------------------|--------------|
| Demographics | | | |
| Age, yrs | 42.8 (11.3) | 55.8 (15.2) | 50.6 (15.0) |
| Male, n (%) | 8 (66.7%) | 12 (66.7%) | 20 (66.7%) |
| Race, White, n (%) | 10 (83.3%) | 13 (72.2%) | 23 (76.7%) |
| Weight, kg | 91.3 (25.1) | 85.1 (17.7) | 87.6 (20.8) |
| BMI, kg/m ² | 32.8 (7.9) | 29.2 (5.3) | 30.6 (6.6) |
| Disease Characteristics | | | |
| PsO disease duration, yrs | 16.5 (12.7) | 17.6 (15.5) | 17.2 (14.2) |
| IGA, moderate (3), n (%) | 12 (100%) | 17 (94.4%) ^a | 29 (96.7%) |
| BSA, % | 8.6 (2.9) | 6.6 (2.8) | 7.4 (3.0) |
| PASI (0-72) ^d | 10.1 (3.1) | 8.5 (2.8) | 9.1 (3.0) |
| ss-IGA ≥1, n (%) | 9 (75.0%) | 11 (61.1%) | 20 (66.7%) |
| f-IGA ≥1, n (%) | 8 (66.7%) | 8 (44.4%) | 16 (53.3%) |
| i-IGA ≥1, n (%) | 7 (58.3%) | 11 (61.1%) | 18 (60.0%) |
| sPGA-G ≥1, n (%) | 5 (41.7%) | 11 (61.1%) | 16 (53.3%) |
| Nail PsO, n (%) | 7 (58.3%) | 8 (44.4%) | 15 (50.0%) |
| Previous Medication Use | | | |
| Topical agents, n (%) ^e | 12 (100%) | 18 (100%) | 30 (100%) |
| Phototherapy, n (%) ^f | 1 (8.3%) | 2 (11.1%) | 3 (10.0%) |
| Conventional systemics, n (%) ^g | 2 (16.7%) | 1 (5.6%) | 3 (10.0%) |
| Advanced orals, n (%) ^h | 0 | 1 (5.6%) | 1 (3.3%) |
| Methotrexate, n (%) | 1 (8.3%) | 0 | 1 (3.3%) |

Data shown are mean (standard deviation) unless otherwise noted. ^aOne GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; ^bMedian (interquartile range) BSA was 8.0% (6.0-10.8%), 8.0% (4.0-8.5%), and 7.0% (5.0-9.0%), respectively; ^cMedian (interquartile range) PASI was 9.8% (8.2-12.5%), 8.6% (6.4-10.6%), and 9.0% (6.6-10.7%), respectively; ^dTopical, anthralin, keratolytics, tar; ^ePUVA, ultraviolet B + PUVA, methotrexate, cyclosporine, acitretin; ^fAcetaminophen, diclofenac; ^gConventional systemics, topical; ^hAdvanced orals, systemic; ⁱss-IGA=site-specific IGA; ^jf-IGA=face, intertriginous IGA; ^kPASI=psoriasis area and severity index; ^lsPGA=site-specific IGA; ^mBSA=body surface area; ⁿBSA=body surface area; ^oBSA=body surface area; ^pBSA=body surface area; ^qBSA=body surface area; ^rBSA=body surface area; ^sBSA=body surface area; ^tBSA=body surface area; ^uBSA=body surface area; ^vBSA=body surface area; ^wBSA=body surface area; ^xBSA=body surface area; 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^{tl}BSA=body surface area; tmBSA=body surface area; ^{tn}BSA=body surface area; ^{to}BSA=body surface area; ^{tp}BSA=body surface area; ^{tq}BSA=body surface area; ^{tr}BSA=body surface area; ^{ts}BSA=body surface area; ^{tt}BSA=body surface area; ^{tu}BSA=body surface area; ^{tv}BSA=body surface area; ^{tw}BSA=body surface area; ^{tx}BSA=body surface area; ^{ty}BSA=body surface area; ^{tz}BSA=body surface area; ^{ua}BSA=body surface area; ^{ub}BSA=body surface area; ^{uc}BSA=body surface area; ^{ud}BSA=body surface area; ^{ue}BSA=body surface area; ^{uf}BSA=body surface area; ^{ug}BSA=body surface area; ^{uh}BSA=body surface area; ^{ui}BSA=body surface area; ^{uj}BSA=body surface area; ^{uk}BSA=body surface area; ^{ul}BSA=body surface area; ^{um}BSA=body surface area; ^{un}BSA=body surface area; ^{uo}BSA=body surface area; ^{up}BSA=body surface area; ^{uq}BSA=body surface area; ^{ur}BSA=body surface area; ^{us}BSA=body surface area; ^{ut}BSA=body surface area; ^{uu}BSA=body surface area; ^{uv}BSA=body surface area; ^{uw}BSA=body surface area; ^{ux}BSA=body surface area; ^{uy}BSA=body surface area; ^{uz}BSA=body surface area; ^{va}BSA=body surface area; ^{vb}BSA=body surface area; ^{vc}BSA=body surface area; ^{vd}BSA=body surface area; ^{ve}BSA=body surface area; ^{vf}BSA=body surface area; ^{vg}BSA=body surface area; ^{vh}BSA=body surface area; ^{vi}BSA=body surface area; ^{vj}BSA=body surface area; ^{vk}BSA=body surface area; ^{vl}BSA=body surface area; ^{vm}BSA=body surface area; ^{vn}BSA=body surface area; ^{vo}BSA=body surface area; ^{vp}BSA=body surface area; ^{vq}BSA=body surface area; ^{vr}BSA=body surface area; ^{vs}BSA=body surface area; ^{vt}BSA=body surface area; ^{vu}BSA=body surface area; ^{vv}BSA=body surface area; ^{vw}BSA=body surface area; ^{vx}BSA=body surface area; ^{vy}BSA=body surface area; ^{vz}BSA=body surface area; ^{wa}BSA=body surface area; ^{wb}BSA=body surface area; ^{wc}BSA=body surface area; ^{wd}BSA=body surface area; ^{we}BSA=body surface area; ^{wf}BSA=body surface area; ^{wg}BSA=body surface area; ^{wh}BSA=body surface area; ^{wi}BSA=body surface area; ^{wj}BSA=body surface area; ^{wk}BSA=body surface area; ^{wl}BSA=body surface area; ^{wm}BSA=body surface area; ^{wn}BSA=body surface area; ^{wo}BSA=body surface area; ^{wp}BSA=body surface area; ^{wq}BSA=body surface area; ^{wr}BSA=body surface area; ^{ws}BSA=body surface area; ^{wt}BSA=body surface area; ^{wu}BSA=body surface area; ^{wv}BSA=body surface area; ^{ww}BSA=body surface area; ^{wx}BSA=body surface area; ^{wy}BSA=body surface area; ^{wz}BSA=body surface area; ^{xa}BSA=body surface area; <