P0408

# SPECTREM: High-Impact Site Skin Clearance and Itch Improvement Through Week 48 With Guselkumab in Participants With Low Body Surface Area, Moderate Psoriasis

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## Key Takeaways

- **GUS treatment provided rapid onset of response across high-impact sites, with complete site-specific skin clearance in 50% of participants achieved in 6–10 weeks**
- **Through Week 48, among participants with low BSA, moderate PsO involving high-impact sites, GUS:**
  - **Provided sustained and meaningful improvements in site-specific skin clearance and itch scores, with >80% of GUS-treated participants experiencing clear or almost clear skin**
  - **Was well tolerated with no new safety signals identified**

## Background

Psoriasis (PsO) affecting high-impact sites (eg, scalp, face, intertriginous regions, or genitals) is often associated with pruritus, pain, and poor quality of life[1-3]; however, these patients often have only a low overall proportion of body surface area (BSA) affected, which has historically limited their access to systemic therapies[3]

The International Psoriasis Council addressed the potential undertreatment of these patients[4] by expanding the criteria for systemic therapy eligibility to include those with disease involving high-impact sites and those who experienced failure of topical therapy[5]

SPECTREM is a phase 3b, randomized, placebo (PBO)-controlled study that evaluated guselkumab (GUS) efficacy and safety in participants with low BSA, moderate plaque PsO involving ≥1 high-impact site that had failed ≥1 topical therapy[6]

- Significant improvements in overall and site-specific skin clearance and patient-reported outcomes (PROs) were previously reported with GUS at Week 16

## Objective

**This analysis reports efficacy at Week 48 and safety through Week 56 of GUS from the final SPECTREM database lock using:**

- Response rates and time to response for
  - Scalp-specific Investigator's Global Assessment (ss-IGA)
  - Facial IGA (f-IGA)
  - Intertriginous IGA (i-IGA)
  - Static Physician Global Assessment of Genitalia (sPGA-G)
- Mean Psoriasis Symptom and Sign Diary (PSSD) itch score
- Adverse events (AEs)

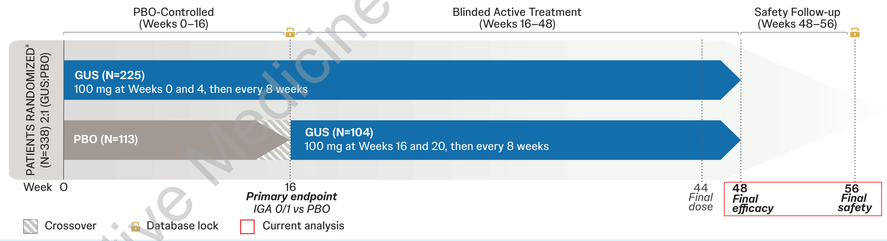
## Methods

***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 of ≥1 prior topical therapy

**Skin clearance[b] through Week 48 was evaluated among participants with baseline site-specific IGA/PGA ≥3 by:**

- ss-IGA 0/1 (absence of/very mild disease) and 0 (absence)
- f-IGA 0/1 (clear/minimal) and 0 (clear)
- i-IGA 0/1 (clear/minimal) and 0 (clear)
- sPGA-G 0/1 (clear/minimal) and 0 (clear)




**PSSD itch score improvement[b] was assessed by:**

- Mean score from baseline through Week 48

*[a]Randomization was stratified by high-impact site. 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. [b]NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders for skin clearance analyses and were accounted for in the PSSD itch analysis model.* ***BSA****=body surface area,* ***f-IGA****=facial IGA,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***i-IGA****=intertriginous IGA,* ***NRI****=nonresponder imputation,* ***PBO****=placebo,* ***PGA****=Physician Global Assessment,* ***PsO****=psoriasis,* ***PSSD****=Psoriasis Symptom and Sign Diary,* ***sPGA****=static PGA of Genitalia,* ***ss-IGA****=scalp-specific IGA.*

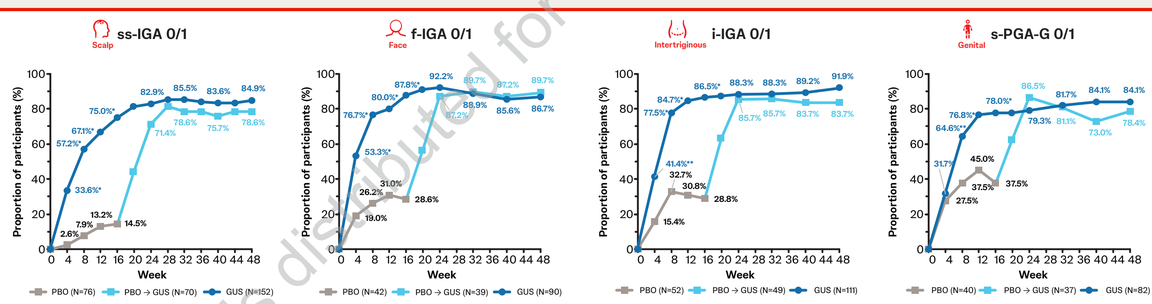
## Results

***Baseline demographics and disease characteristics were generally balanced between the PBO and GUS groups***

| Baseline Characteristics | | PBO (N=113) | GUS (N=225) | Total (N=338) |
|---|---|---|---|---|
| **Demographics** | | | | |
| | **Age,** yrs | 44.5 (14.9) | 47.0 (14.7) | 46.2 (14.8) |
| | **Male** | 57 (50.4%) | 116 (51.6%) | 173 (51.2%) |
| | **Race,** White | 83 (73.5%) | 166 (73.8%) | 249 (73.7%) |
| | **Weight,** kg | 87.4 (20.6) | 88.4 (22.4) | 88.1 (21.8) |
| | **BMI,** kg/m$^2$ | 31.0 (7.5) | 30.9 (7.5) | 30.9 (7.5) |
| **Disease Characteristics** | | | | |
| | **PsO disease duration,** yrs | 14.0 (11.9) | 18.4 (14.9) | 16.9 (14.1) |
| | **IGA,** moderate (3) | 113 (100%) | 224 (99.6%)[a] | 337 (99.7%) |
| | **BSA,** %[b] | 7.5 (3.7) | 7.6 (3.7) | 7.6 (3.7) |
| | **PASI** (0–72) | 9.0 (3.9) | 9.1 (3.8) | 9.0 (3.8) |
| | **ss-IGA,** moderate-to-severe (≥3) | 76 (67.3) | 152 (67.6) | 228 (67.5) |
| | **f-IGA,** moderate-to-severe (≥3) | 42 (37.2) | 90 (40.0) | 132 (39.1) |
| | **i-IGA,** moderate-to-severe (≥3) | 52 (46.0) | 111 (49.3) | 163 (48.2) |
| | **sPGA-G,** moderate-to-severe (≥3) | 40 (35.4) | 82 (36.4) | 122 (36.1) |
| **Previous Medication Use** | | | | |
| | **Topical agents**[c] | 113 (100%) | 225 (100%) | 338 (100%) |
| | **Phototherapy**[d,e] | 16 (14.3%) | 46 (20.5%) | 62 (18.5%) |
| | **Conventional systemics**[d,f] | 15 (13.4%) | 31 (13.8%) | 46 (13.7%) |
| | **Advanced orals**[d,g] | 4 (3.6%) | 11 (4.9%) | 15 (4.5%) |

*Data shown are mean (SD) unless otherwise noted. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; [b]Median (interquartile range) BSA was 7.0% (4.5–10.1%), 7.2% (4.3–10.7%), and 7.0% (4.3–10.5%), respectively; [c]Topical, anthralin, keratolytics, tar; [d]PBO N=112, GUS N=224, Total N=336; [e]PUVA, UVB; [f]PUVA, methotrexate, cyclosporine, acitretin; [g]Apremilast, deucravacitinib.* ***BMI****=body mass index,* ***BSA****=body surface area,* ***f-IGA****=facial IGA,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***i-IGA****=intertriginous IGA,* ***PASI****=Psoriasis Area Severity Index,* ***PBO****=placebo,* ***PsO****=psoriasis,* ***PUVA****=psoralen plus ultraviolet,* ***SD****=standard deviation,* ***sPGA****=static PGA of Genitalia,* ***ss-IGA****=scalp-specific IGA,* ***UVB****=ultraviolet B,* ***yrs****=years.*

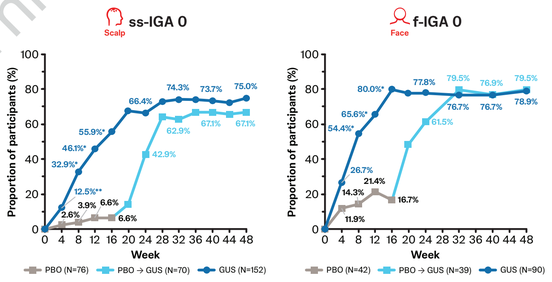
***More than 80% of GUS-randomized participants achieved clear or almost clear skin at high-impact sites; response rates on GUS treatment were either maintained or increased through Week 48 (NRI)***




***$p$<0.001, **$p$<0.05 GUS vs PBO**

*p-value is based on the chi-squared test and not adjusted for baseline stratification factor. Only participants with baseline site-specific IGA/PGA ≥3 were included. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. 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 in the PBO → GUS group.* ***f-IGA****=facial IGA,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***i-IGA****=intertriginous IGA,* ***NRI****=nonresponder imputation,* ***PBO****=placebo,* ***PGA****=Physician Global Assessment,* ***PsO****=psoriasis,* ***s-PGA-G****=static Physician Global Assessment of Genitalia,* ***ss-IGA****=scalp-specific IGA.*

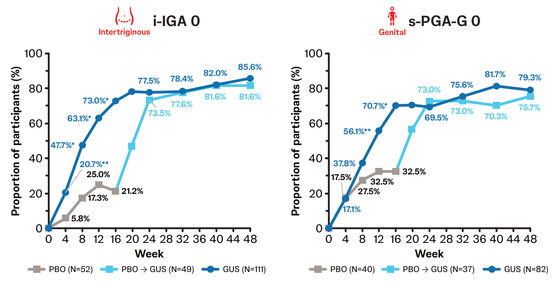
***More than 70% of GUS-randomized participants achieved complete skin clearance of scalp and facial PsO; response rates on GUS treatment were either maintained or increased through Week 48 (NRI)***




***nominal $p$<0.001, **nominal $p$<0.05 GUS vs PBO**

*p-value is based on the chi-squared test and not adjusted for baseline stratification factor. Only participants with baseline site-specific IGA/PGA ≥3 were included. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. 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 in the PBO → GUS group.* ***f-IGA****=facial IGA,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***NRI****=nonresponder imputation,* ***PBO****=placebo,* ***PGA****=Physician Global Assessment,* ***PsO****=psoriasis, s-****PGA-G****=static Physician Global Assessment of Genitalia,* ***ss-IGA****=scalp-specific IGA.*

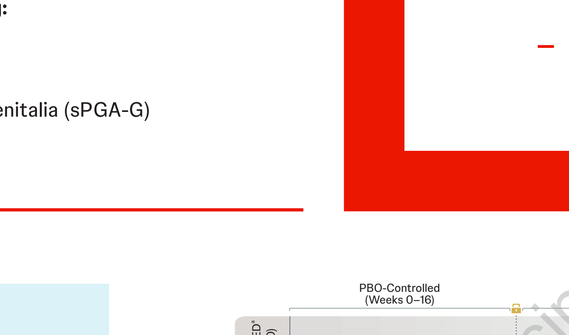
***More than 75% of GUS-randomized participants achieved complete skin clearance of intertriginous and genital PsO; response rates on GUS treatment were either maintained or increased through Week 48 (NRI)***




***nominal $p$<0.001, **nominal $p$<0.05 GUS vs PBO**

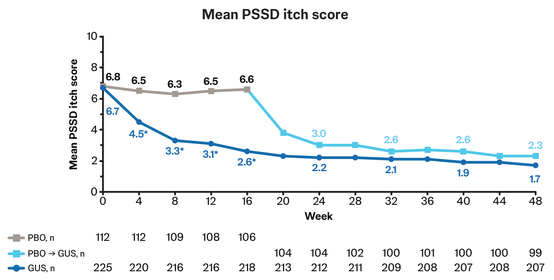
*p-value is based on the chi-squared test and not adjusted for baseline stratification factor. Only participants with baseline site-specific IGA/PGA ≥3 were included. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. 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 in the PBO → GUS group.* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***i-IGA****=intertriginous IGA,* ***NRI****=nonresponder imputation,* ***PBO****=placebo,* ***PGA****=Physician Global Assessment,* ***PsO****=psoriasis,* ***sPGA****=static PGA of Genitalia.*

***Speed of Response: Complete site-specific skin clearance in 50% of GUS-randomized participants was achieved in 6–10 weeks***




***f-IGA****=facial IGA,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***i-IGA****=intertriginous IGA,* ***PGA****=Physician Global Assessment,* ***sPGA-G****=static PGA of Genitalia,* ***ss-IGA****=scalp-specific IGA.*

***The GUS-randomized group achieved a meaningful 5-point improvement in mean PSSD itch score; response on GUS treatment was either maintained or improved through Week 48 (NRI)***




***$p$<0.001 GUS vs PBO change from baseline**

*p-value is based on the MMRM with treatment group, visit, baseline score, high-impact site (scalp, face, intertriginous, genital), an interaction term of visit with treatment group, and an interaction term of visit with baseline score as explanatory variables. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to the designated visit were considered nonresponders from that point forward. Participants with missing data were accounted for in the analysis model. 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 in the PBO → GUS group.* ***GUS****=guselkumab,* ***MMRM****=mixed models for repeated measures,* ***NRI****=nonresponder imputation,* ***PBO****=placebo,* ***PsO****=psoriasis,* ***PSSD****=Psoriasis Symptom and Sign Diary.*

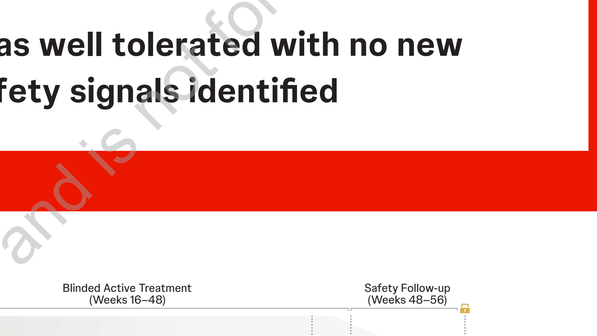
***Photographic scalp skin clearance journey for a participant randomized to GUS***




***Photographic facial skin clearance journey for a participant randomized to GUS (cross-polarized)***




***Photographic intertriginous skin clearance journey for a participant randomized to GUS***




***GUS was generally well tolerated; safety findings through the final safety follow-up visit (Week 56) were consistent with the established GUS safety profile with no new safety signals***

| | Weeks 0–16 | | Weeks 16–56 | Weeks 0–56 |
|---|---|---|---|---|
| **Safety Analysis Set** | **PBO (N=113)** | **GUS (N=225)** | **PBO→GUS (N=104)[a]** | **GUS (N=225)** |
| **Mean weeks of follow-up** | 15.8 | 15.9 | 38.5 | 53.4 |
| **Participants with ≥1 AE** | 45 (39.8%) | 85 (37.8%) | 56 (53.8%) | 138 (61.3%) |
| AEs leading to discontinuation of study agent | 4 (3.5%) | 0 | 1 (1.0%) | 4 (1.8%) |
| Serious AEs | 1 (0.9%) | 3 (1.3%) | 2 (1.9%) | 12 (5.3%) |
| **Participants with ≥1 AE of interest** | | | | |
| **Infections** | 23 (20.4%) | 50 (22.2%) | 42 (40.4%) | 85 (37.8%) |
| Serious infections | 1 (0.9%)[b] | 0 | 1 (1.0%)[c] | 2 (0.9%)[d] |
| **MACE** | 0 | 1 (0.4%)[e,f] | 0 | 4 (1.8%)[e,f] |
| **Malignancy** | 0 | 0 | 0 | 2 (0.9%)[g] |
| NMSC | 0 | 0 | 0 | 2 (0.9%)[g] |
| Excluding NMSC | 0 | 0 | 0 | 0 |
| **VTE** | 0 | 0 | 0 | 1 (0.4%)[e,h] |
| **Serum-like sickness or anaphylaxis** | 0 | 0 | 0 | 0 |
| **Active tuberculosis** | 0 | 0 | 0 | 0 |
| **Inflammatory bowel disease** | 0 | 0 | 0 | 0 |

*Participants were counted only once for any given event, regardless of the number of times they experienced the event. AEs were coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 26.1. [a]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 in the PBO → GUS group; [b]One participant had pneumonia; [c]One participant had appendicitis; [d]One participant had a pelvic abscess and one participant had acute osteomyelitis of the cervical spine and sepsis; [e]Participants had relevant cardiovascular risk factors; [f]During Weeks 0-16, one participant had a cerebrovascular accident; from Weeks 16-56, one participant had a myocardial infarction, one participant had coronary artery occlusion, and one participant had unstable angina; [g]Two participants had basal cell carcinoma; [h]One participant had bilateral pulmonary embolism.* ***AE****=adverse event,* ***GUS****=guselkumab,* ***MACE****=major adverse cardiovascular event,* ***NMSC****=non-melanoma skin cancer,* ***PBO****=placebo,* ***VTE****=venous thromboembolism.*

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