SPECTREM: Guselkumab Demonstrates Consistent Significant Clearance Across the Full Range of Low Body Surface Area, Moderate Psoriasis With Special Sites Involvement

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Background

SPECTREM is an ongoing phase 3b, multicenter, randomized, double-blind, placebo (PBO)-controlled study evaluating the efficacy and safety of guselkumab (GUS) in participants with low body surface area (BSA), moderate plaque psoriasis (PsO) involving ≥1 high-impact site

Patients with low BSA PsO who may be more effectively treated with systemic therapies are underrepresented in clinical studies

SPECTREM was intentionally designed to address the undertreatment of patients with low BSA PsO involving high-impact sites

Objectives

To evaluate efficacy of GUS vs PBO at Week 16 using:

- Investigator's Global Assessment (IGA)
- Psoriasis Area and Severity Index (PASI)
- Body surface area (BSA)

To evaluate safety in SPECTREM participants through Week 16:

- Adverse events (AEs)
- Serious adverse events (SAEs)

Methods

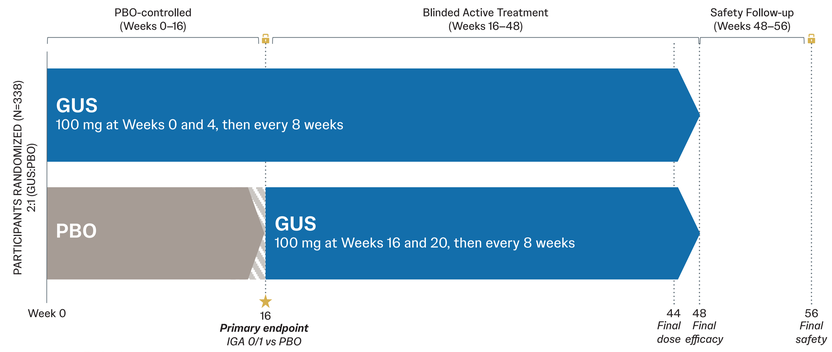
Key Inclusion Criteria

- IGA=3
- BSA=2–15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact site with at least moderate severity (scalp, face, intertriginous, genital)

A total of 338 participants were randomized to receive GUS (N=225) or PBO (N=113)

Endpoints presented at Week 16 include:

- Primary endpoint: proportion of participants achieving IGA 0/1
- Key major secondary endpoints:
  - Proportions of participants achieving PASI 90, IGA 0, and PASI 100
  - Mean percent improvements from baseline in BSA and PASI



▨=crossover. 🔒=database lock.

***GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **PBO**=placebo, **vs**=versus.*

Key Takeaways

- **Guselkumab is highly effective in participants with low BSA, moderate plaque psoriasis with high-impact site involvement; at Week 16:**
  - ✓ **More than 70% of GUS-randomized participants achieved the primary endpoint (IGA 0/1)**
  - ✓ **More than 30% of GUS-randomized participants achieved complete skin clearance (IGA 0 and PASI 100)**
  - ✓ **Mean percent improvements in BSA and PASI were >80% for the GUS group**
- **Consistent, significant improvements across multiple skin clearance measures, irrespective of baseline BSA, support the efficacy of guselkumab across a broad range of patients with PsO**
- **No new safety signals were identified**

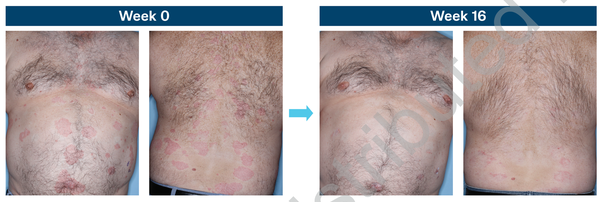
Results

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

	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%)
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, %	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)
Previous Medication Use			
Topical agents[b]	113 (100%)	225 (100%)	338 (100%)
Phototherapy[c,d]	16 (14.3%)	46 (20.5%)	62 (18.5%)
Conventional systemics[c,e]	15 (13.4%)	31 (13.8%)	46 (13.7%)
Advanced orals[c,f]	4 (3.6%)	11 (4.9%)	15 (4.5%)

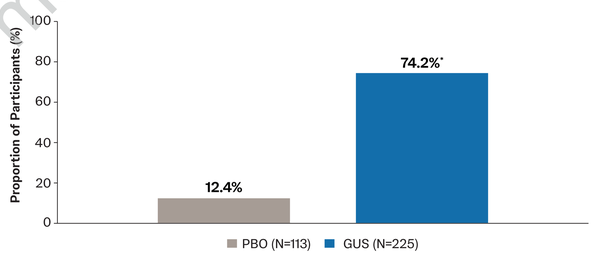
*Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; [b]Topical, anthralin, keratolytics, tar; [c]PBO N=112, GUS N=224, Total N=336; [d]PUVA, UVB; [e]PUVA, methotrexate, cyclosporine, acitretin; [f]Apremilast, deucravacitinib. **BMI**=body mass index, **BSA**=body surface area, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **PUVA**=psoralen plus ultraviolet A, **SD**=standard deviation, **UVB**=ultraviolet B, **Yrs**=years.*

A GUS-randomized participant who achieved the primary endpoint (IGA 0/1) at Week 16



***BSA**=body surface area, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index.*

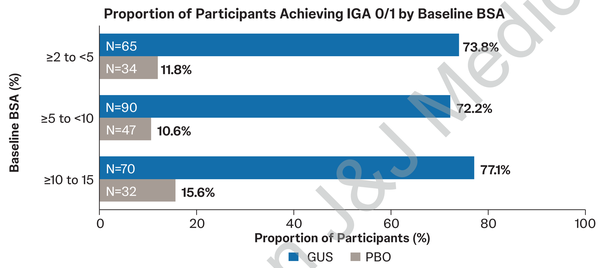
A significantly greater proportion of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16



p<0.001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel (CMH) test stratified by high-impact site (scalp, face, intertriginous, genital). Nonresponder imputation (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 designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **GUS=guselkumab, **IGA**=Investigator's Global Assessment, **PBO**=placebo, **PsO**=psoriasis.*

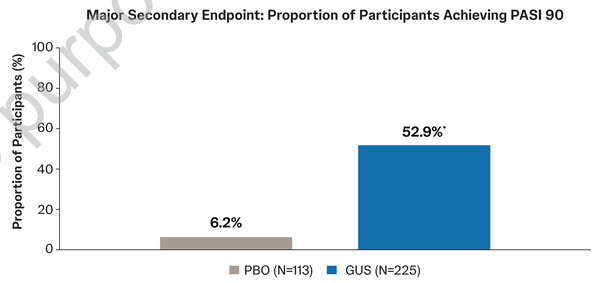
More than 70% of GUS-randomized participants achieved IGA 0/1 at Week 16, regardless of baseline BSA

- On average, 74.4% GUS-randomized participants achieved IGA 0/1



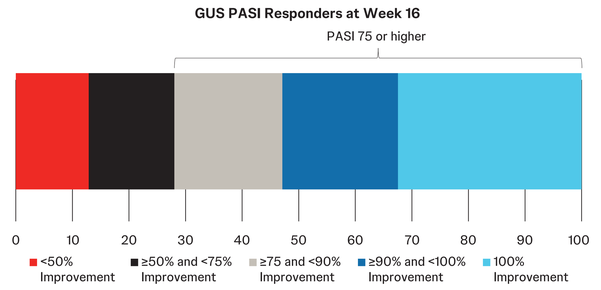
*NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **BSA**=body surface area, **GUS**=guselkumab, **NRI**=nonresponder imputation, **PBO**=placebo, **PsO**=psoriasis.*

A significantly greater proportion of GUS-randomized participants achieved PASI 90 compared to PBO-randomized participants at Week 16



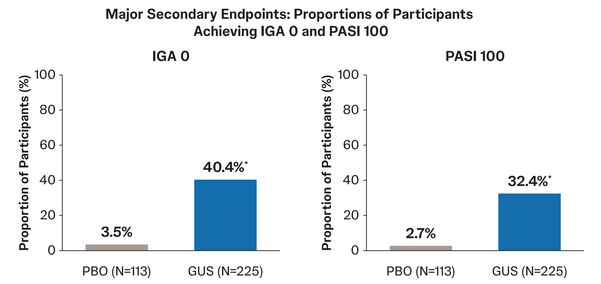
p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **CMH= Cochran-Mantel-Haenszel, **GUS**=guselkumab, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis.*

72.0% of GUS-randomized participants achieved a PASI 75 or higher response at Week 16



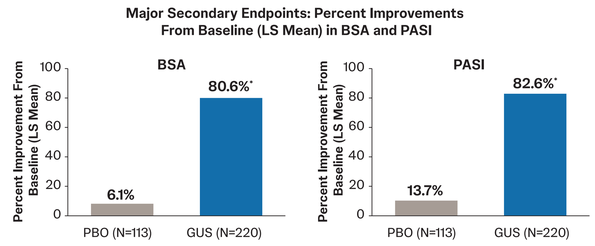
*NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **GUS**=guselkumab, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PsO**=psoriasis.*

Significantly greater proportions of GUS- vs PBO-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) at Week 16



p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). 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 designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **CMH=Cochran-Mantel-Haenszel, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis.*

Mean percent improvements in BSA and PASI were significantly greater for the GUS group compared to the PBO group at Week 16



p<0.001 GUS vs PBO; p-value is based on the mixed-effect model for repeated measures (MMRM) with explanatory variables of treatment group, visit, baseline score, high-impact site, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. When participants discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment, zero change was assigned from that point onward. Missing data were handled by MMRM under missing at random assumption. **BSA=body surface area, **GUS**=guselkumab, **LS Mean**=least squares mean, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis.*

Safety outcomes were consistent with the established safety profile of GUS and no new safety signals were identified

	PBO (N=113)	GUS (N=225)
Safety Outcomes Through Week 16		
Average duration of follow-up (weeks)	15.8	15.9
Participants with ≥1 AE	45 (39.8%)	85 (37.8%)
Participants with ≥1 AE leading to discontinuation of study agent	4 (3.5%)	0
Participants with ≥1 serious AE	1 (0.9%)	3 (1.3%)[g]
Participants with ≥1 injection site reaction	1 (0.9%)	6 (2.7%)[h]
Infections	23 (20.4%)	50 (22.2%)
Serious infections	1 (0.9%)	0
Major adverse cardiovascular event	0	1 (0.4%)[i]

- **No cases of malignancy, active tuberculosis, inflammatory bowel disease, serum sickness/anaphylaxis, or death were reported**

*Participants were counted only once for any given event, regardless of the number of times they experienced the event. AEs were coded using MedDRA Version 26.1. [g]One event each of upper limb fracture, renal colic, and cerebrovascular accident; [h]Of the 6 injection site reactions, 4 were mild and 2 were moderate, none led to discontinuation; [i]The one major adverse cardiovascular event was a cerebrovascular accident within the first week of enrollment; the participant had a history of prior transient ischemic attack. **AE**=adverse event, **GUS**=guselkumab, **MedDRA**=Medical Dictionary for Regulatory Activities, **PBO**=placebo.*

GUS-randomized participants who achieved IGA 0 and 100% improvement in BSA and PASI at Week 16

***BSA**=body surface area, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index.*

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