SPECTREM: Guselkumab Efficacy and Patient-Reported Outcomes Across Multiple High-Impact Sites in Participants With Low BSA, Moderate Psoriasis

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Background

- SPECTREM was a 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 sites
- 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, and most SPECTREM participants had more than one high-impact site involved

Objectives

To evaluate efficacy of GUS vs PBO in participants with at least moderate high-impact site involvement (site-specific Investigator's Global Assessment [IGA]/Physician's Global Assessment [PGA] ≥3 at baseline) at Week 16 via:

- High-impact site-specific IGA
  - Scalp-specific IGA (ss-IGA)
  - Facial IGA (f-IGA)
  - Intertriginous IGA (i-IGA)
  - Static PGA of Genitalia (sPGA-G)
- Psoriasis Symptoms and Signs Diary (PSSD)
- Dermatology Life Quality Index (DLQI)
- Psoriasis Area and Severity Index (PASI)

Methods

Key inclusion criteria:

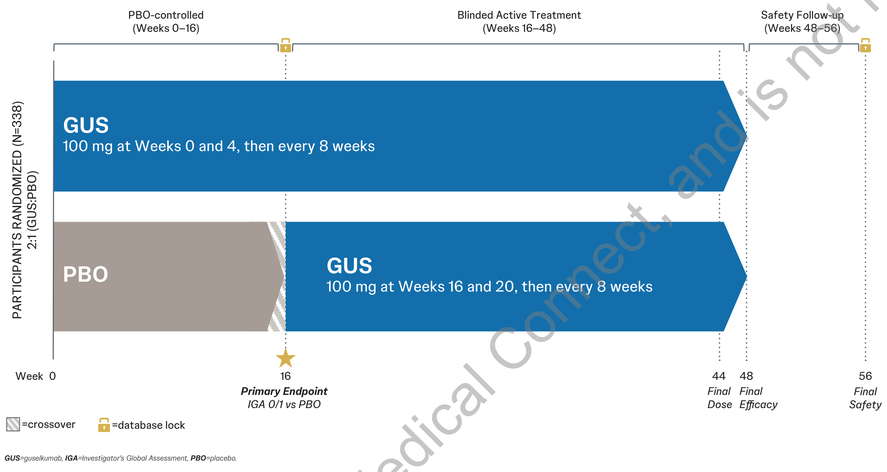
- IGA=3
- BSA=2–15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact sites with at least moderate severity (scalp, face, intertriginous, genital)

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
- Proportions of participants achieving overall IGA 0/1 and PASI 90 by number of high-impact sites (one, two, three, or four sites[a]) at baseline
- Proportions of participants achieving ss-IGA 0/1, f-IGA 0/1, i-IGA 0/1, and sPGA-G 0/1 by number of high-impact sites (one, two, three, or four sites[a]) at baseline
- Patient-reported outcomes by number of high-impact sites (one, two, three, or four sites[a]) at baseline:
  - Mean change in PSSD total symptoms score
  - Proportion of participants achieving a ≥4-point improvement in PSSD itch score
  - Proportion of participants achieving DLQI 0/1

[a]Participants grouped into one, two, three, and four high-impact sites are mutually exclusive.



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

Key Takeaways

- **SPECTREM enrolled a population that is often undertreated (i.e., low BSA psoriasis with high-impact site involvement). At baseline, >80% of participants had psoriasis affecting ≥2 high-impact sites.**
- **After just 3 doses of GUS, 60–85% of GUS-randomized participants achieved clear/almost clear skin (IGA 0/1) regardless of the number of high-impact sites involved**
- **A majority of GUS-randomized participants achieved meaningful improvements in itch and patient-reported quality of life, regardless of the number of high-impact sites involved**

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%)
	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%)[b]	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)
Participants with any severity of PsO at high-impact sites (site-specific IGA/PGA ≥1)				
	One site	18 (15.9%)	43 (19.1%)	61 (18.0%)
	Two sites	43 (38.1%)	73 (32.4%)	116 (34.3%)
	Three sites	29 (25.7%)	69 (30.7%)	98 (29.0%)
	Four sites	23 (20.4%)	40 (17.8%)	63 (18.6%)
Participants with moderate-to-severe PsO at high-impact sites (site-specific IGA/PGA ≥3)				
	One site	41 (36.3%)	81 (36.0%)	122 (36.1%)
	Two sites	53 (46.9%)	91 (40.4%)	144 (42.6%)
	Three sites	13 (11.5%)	40 (17.8%)	53 (15.7%)
	Four sites	6 (5.3%)	13 (5.8%)	19 (5.6%)
Previous medication use				
	Topical agents[c] (N=338)	100%		
	Phototherapy[d] (N=336)	18.5%		
	Systemics[e] (N=336)	13.7%		
	Advanced orals[f] (N=336)	4.5%		

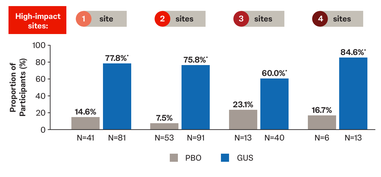
*Data shown are mean (SD), unless otherwise indicated. [b]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [c]Topical, anthralin, keratolytics, and tar; [d]PUVA and UVB; [e]PUVA, methotrexate, cyclosporine, and acitretin; [f]Apremilast and deucravacitinib.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

- No notable differences in baseline high-impact site involvement were observed between treatment groups
- At baseline, a majority of participants had PsO affecting two or more high-impact sites (any severity, site-specific IGA/PGA >0)
- Most participants assessed in this analysis had moderate-to-severe PsO (site-specific IGA/PGA ≥3) at one or two high-impact sites

Greater proportions of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16

- ≥60% of GUS-randomized participants achieved IGA 0/1 across the number of high-impact sites involved at baseline

Proportion of Participants Achieving IGA 0/1 by Number of High-Impact Sites at Baseline[g]

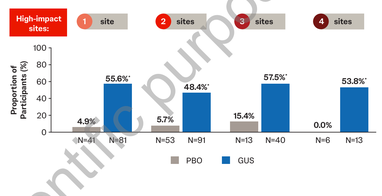


*nominal p<0.05 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. [a]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) score ≥3. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PBO**=placebo, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=site-specific IGA.*

Greater proportions of GUS-randomized participants achieved PASI 90 compared to PBO-randomized participants at Week 16

- Approximately half of GUS-randomized participants achieved PASI 90 across the number of high-impact sites involved at baseline

Proportion of Participants Achieving PASI 90 by Number of High-Impact Sites at Baseline[h]



*nominal p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. 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. [a]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) score ≥3. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=scalp-specific IGA.*

Greater proportions of GUS-randomized participants achieved PASI 90 compared to PBO-randomized participants at Week 16

- Approximately half of GUS-randomized participants achieved PASI 90 across the number of high-impact sites involved at baseline

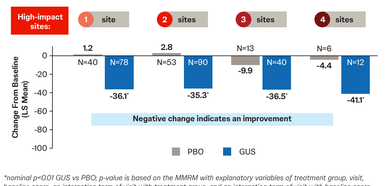
Proportion of Participants Achieving PASI 90 by Number of High-Impact Sites at Baseline[h]

*nominal p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. 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. [a]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) score ≥3. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **IGA**=Investigator's Global Assessment, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=scalp-specific IGA.*

The GUS groups achieved generally comparable mean changes from baseline in PSSD total symptoms scores at Week 16, regardless of number of high-impact sites involved at baseline

- Mean changes from baseline in PSSD total symptoms scores were >35 for the GUS groups across the number of sites involved at baseline

Mean Change From Baseline (LS Mean) in PSSD Total Symptoms Score by Number of High-Impact Sites at Baseline[i]

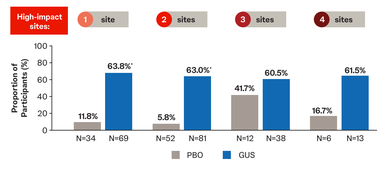


*nominal p<0.001 GUS vs PBO; p-value is based on the MMRM with explanatory variables of treatment group, visit, baseline score, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. [i]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, or sPGA-G) score ≥3. Threshold for clinically meaningful improvement in PSSD symptoms score is ≥40 points.[j] When participants discontinued study agent due to lack of efficacy, worsening of psoriasis, 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. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **IHGA**=intertriginous IGA, **LS**=least-squares, **MMRM**=mixed-model for repeated measures, **PBO**=placebo, **PSSD**=Psoriasis Symptoms and Signs Diary, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=site-specific IGA.*

Greater proportions of GUS-randomized vs PBO-randomized participants achieved a ≥4-point reduction (improvement) from baseline in PSSD itch score at Week 16

- >60% of GUS-randomized participants achieved a ≥4-point reduction from baseline in PSSD itch score, regardless of number of sites involved at baseline

Proportion of Participants Achieving a ≥4-point Reduction (Improvement) From Baseline in PSSD Itch Score by Number of High-Impact Sites at Baseline[j]

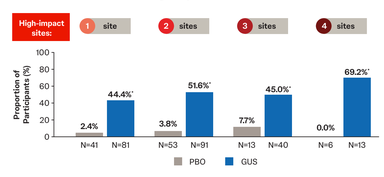


*nominal p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) score ≥3 and a baseline PSSD itch score ≥4. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PBO**=placebo, **PsO**=psoriasis, **PSSD**=Psoriasis Symptoms and Signs Diary, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=site-specific IGA.*

Greater proportions of GUS-randomized participants had no effect of PsO on their quality of life compared to PBO-randomized participants at Week 16

- >44% of GUS-randomized participants achieved a DLQI score of 0/1 (no effect on quality of life) at Week 16, regardless of number of sites involved at baseline

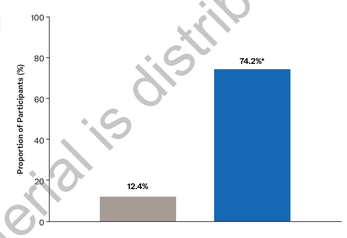
Proportion of Participants Achieving a DLQI Score of 0/1 by Number of High-Impact Sites at Baseline[k]



*nominal p<0.05 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. 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. [a]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) score ≥3. **DLQI**=Dermatology Life Quality Index, **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PBO**=placebo, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=site-specific Investigator's Global Assessment.*

74% of GUS-randomized participants achieved the primary endpoint (IGA 0/1) at Week 16

Primary Endpoint: Proportion of Participants Achieving IGA 0/1

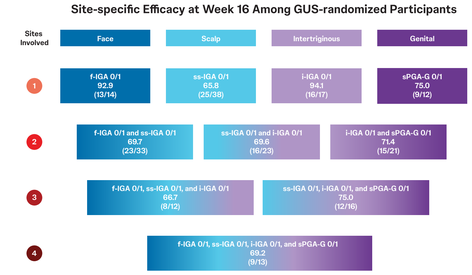


p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by high-impact site (scalp, face, and genitalia/anus; genital). NRI was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered 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, **PBO**=placebo, **PsO**=psoriasis.*

Proportions of participants achieving at least one high-impact site assessment score (ss-IGA, f-IGA, i-IGA, and/or sPGA-G) of 0/1 at Week 16

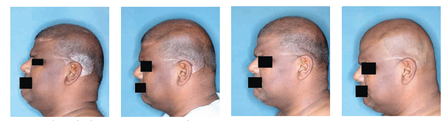
- In GUS-randomized participants with more than 1 high-impact site involved at baseline, more than 2/3 of participants achieved skin clearance (site-specific IGA/PGA 0/1) in all involved sites

Site-specific Efficacy at Week 16 Among GUS-randomized Participants



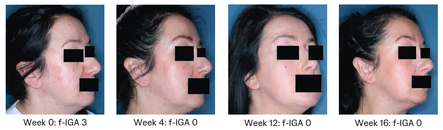
*Groups are mutually exclusive and include participants with baseline high-impact site scores ≥3 who achieved respective site scores of 0/1 at Week 16. Data are shown for groups with ≥10 participants. NRI was used; participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. **f-IGA**=facial Investigator's Global Assessment, **GUS**=guselkumab, **i-IGA**=intertriginous IGA, **NRI**=nonresponder imputation, **PsO**=psoriasis, **sPGA-G**=static Physician's Global Assessment of Genitalia, **ss-IGA**=scalp-specific IGA.*

GUS-randomized participant who achieved ss-IGA 0 at Week 16



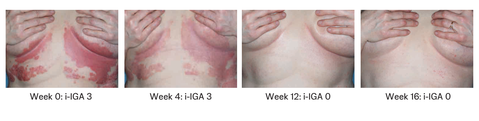
ss-IGA=site-specific Investigator's Global Assessment.

GUS-randomized participant who achieved f-IGA 0 at Week 16



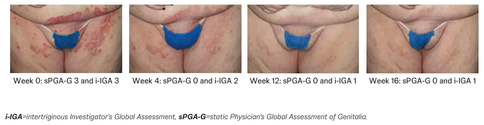
f-IGA=facial Investigator's Global Assessment.

GUS-randomized participant who achieved i-IGA 0 at Week 16



*Participant also had f-IGA=1 and ss-IGA=3 at Week 0 and achieved f-IGA=0 and ss-IGA=0 at Week 48. **f-IGA**=facial Investigator's Global Assessment, **i-IGA**=intertriginous IGA, **ss-IGA**=site-specific IGA.*

GUS-randomized participant with genital and intertrigenous PsO who achieved sPGA-G 0 and i-IGA 1 at Week 16



*i-IGA=intertriginous Investigator's Global Assessment, **sPGA-G**=static Physician's Global Assessment of Genitalia.*

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