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

Stephen K. Tyring,[1] Angela Y. Moore,[2,3] Harrison Nguyen,[4,5] Nicole Seminara,[6] Henry Yu,[7] Theodore Alkousakis,[8] Olivia Choi,[8] Katelyn Rowland,[8] Daphne Chan,[8] Jenny Jeyarajah,[8] Lorne Albrecht[9,10]

[1]Center for Clinical Studies, Webster, TX, USA; [2]Baylor University Medical Center, Dallas, TX, USA; [3]Arlington Research Center, Arlington, TX, USA; [4]Harrison Dermatology and Research Group, Houston, TX, USA; [5]University of Houston College of Medicine, Houston, TX, USA; [6]Piedmont Plastic Surgery and Dermatology, Denver, NC, USA; [7]West Derm Center, Bronx, NY, USA; [8]Johnson & Johnson, Horsham and Spring House, PA, USA; [9]Enverus Medical Research, Surrey, BC, Canada; [10]University of British Columbia, Vancouver, BC, Canada

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 IGA/PGA ≥3 at baseline) at Week 16 via:

- High-impact site-specific Investigator's Global Assessment (IGA)
  - Scalp-specific IGA (ss-IGA)
  - Facial IGA (f-IGA)
  - Intertriginous IGA (i-IGA)
  - Static Physician's Global Assessment 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:

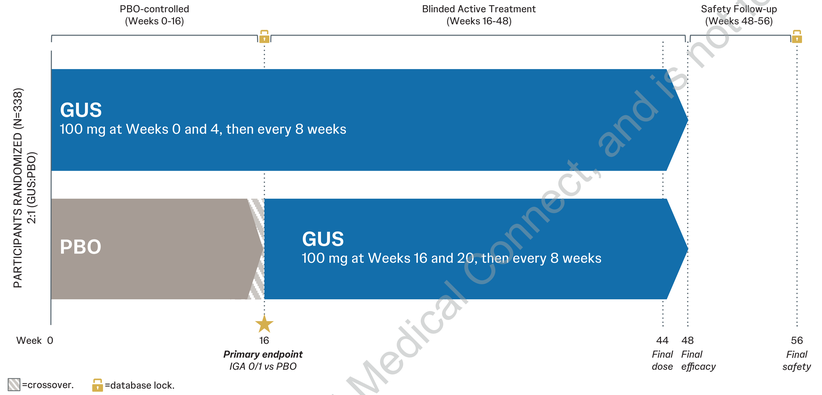
- IGA=3
- BSA=2-15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact sites with at least moderate severity (scalp, face, intertriginous, genital)

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.



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 (100.0%)	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)	Phototherapy[d] (N=336)	Systemics[e] (N=336)	Advanced Orals[f] (N=336)
100%	18.5%	13.7%	4.5%

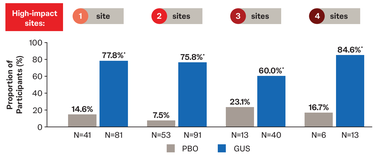
*Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]Topical, anthralin, keratolytics, and tar; [c]PUVA and UVB; [d]PUVA, methotrexate, cyclosporine, and acitretin; [e]Apremilast and deucravacitinib. **BMI**=body mass index; **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]

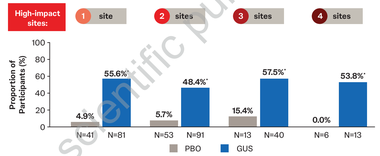


*nominal p=0.05 GUS vs PBO. p-value is based on the chi-squared test, not adjusted for baseline stratification factor. Nonresponder imputation (NRI) was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated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

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]

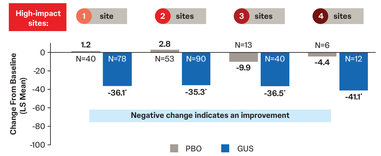


*nominal p=0.05 GUS vs PBO. p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders 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.

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]

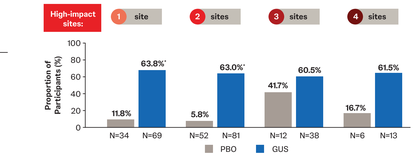


*nominal p=0.01 GUS vs PBO. p-value is based on the MMRM with explanatory variables of treatment group, visit, baseline score, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. [a]Among participants with a baseline high-impact site assessment (ss-IGA, f-IGA, i-IGA, or sPGA-G) score ≥3. [b]Threshold for clinically meaningful improvement in PSSD symptoms score is ≥4.0 points. [c]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. **MMRM**=mixed-model for repeated measures.

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]

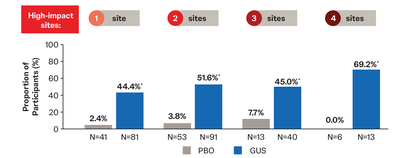


*nominal p<0.001 GUS vs PBO. p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders 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.

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

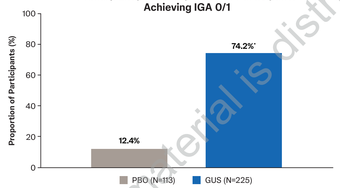
Proportion of Participants Achieving a DLQI Score of 0/1 by Number of High-Impact Sites at Baseline[k]



*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.

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

Primary Endpoint: Proportion of Participants Achieving IGA 0/1

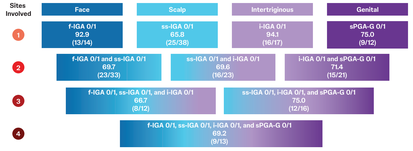


*p<0.001 GUS vs PBO. p-value is based on the Cochran-Mantel-Haenszel (CMH) test stratified by high-impact site (scalp, face, intertriginous, genital). NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated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

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

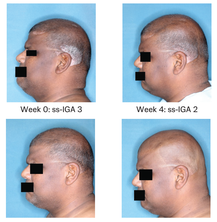
- In GUS-randomized participants with more than 1 high-impact site involved at baseline, more than 2/3 of participants achieved skin clearance (site-specific IGA/PGA 0/1) in all involved sites

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

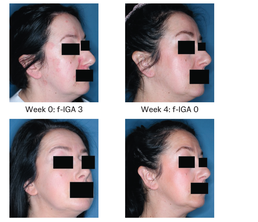


Groups are mutually exclusive and include participants with baseline high-impact site scores ≥3 who achieved respective site scores of 0/1 at Week 16. Data are shown for groups with ≥10 participants. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.

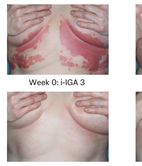
GUS-randomized participant who achieved ss-IGA 0 at Week 16



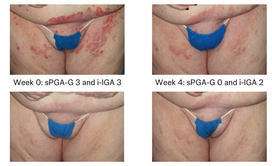
GUS-randomized participant who achieved f-IGA 0 at Week 16



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



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

PRESENTED AT: Maui Derm NP+PA Summer 2025, June 18-21, 2025; Colorado Springs, CO, USA. **REFERENCES: 1.** Armstrong A. et. al. *J Dermatolog Treat.* 2018;30(2):134. **ACKNOWLEDGMENTS:** Medical writing support was provided by Jackie Johnson and Amy C. Porter, employees of Certara, under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175(9):1298-1304). Sponsored by Johnson & Johnson, Horsham, PA, USA. **DISCLOSURES: HN:** has received speakers' bureau and/or honoraria from Amgen, Apogee, Bristol Myers Squibb, Castle Biosciences, Dermavant, Galderma, Johnson & Johnson, LEO, Novartis, Pfizer, Regeneron, SUN, UCB, and Verrica. **NS:** receives consulting fees from AbbVie, Dermavant, Eli Lilly, Galderma , Johnson & Johnson, Pfizer, SUN, and UCB. **HY:** has received honoraria, consulting fees, speaker bureau's from AbbVie, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Johnson & Johnson, LEO, Pfizer, SUN, and UCB. **AM:** receives honoraria or research grants from AbbVie, Acelyrin, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Johnson & Johnson, Novartis, Pfizer, Sanofi, Takeda, and UCB. **LA:** has received grants, sponsored research, speakers' bureau, honoraria, and/or consulting fees from AbbVie, Alumis, Amgen, Arcutis, Aristea, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Dermavant, Dermira, DICE, Eli Lilly, Evolo, Galderma, Horizon, Incyte, Johnson & Johnson, LEO, Merck, Nektar, Novartis, Pfizer, Sanofi, SUN, Takeda, and UCB. **TA, DC, KR, and JJ:** are employees and stockholders of Johnson & Johnson. **OC** is a former employee of Johnson & Johnson.