SPECTREM: Guselkumab Demonstrates Consistent Complete Clearance at Week 16 Across Special Sites in Participants with Low Body Surface Area, Moderate Psoriasis

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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 special sites

Patients with low BSA PsO are underrepresented in clinical studies or undertreated despite being candidates for systemic treatment[1–3]

SPECTREM was intentionally designed to address the knowledge gap of patients with low BSA PsO involving special sites to support treatment of this patient population

Objectives

To evaluate Week 16 GUS vs PBO efficacy via:
- **Investigator's Global Assessment (IGA)**
- **Psoriasis Area and Severity Index (PASI)**
- **Body Surface Area (BSA)**
- **Special site assessments**
  - Scalp-specific IGA (ss-IGA)
  - Facial IGA (f-IGA)
  - Intertriginous IGA (i-IGA)
  - Static Physician's Global Assessment of Genitalia (sPGA-G)

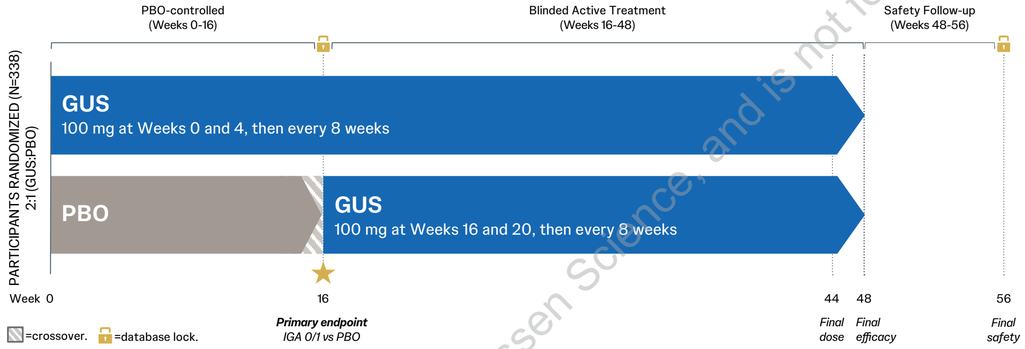
To evaluate safety in SPECTREM participants

Methods

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

Key Inclusion Criteria
- IGA=3
- BSA=2-15% with ≥1 plaque outside of special sites
- ≥1 special site with at least moderate severity (scalp, face, intertriginous, genital)

Endpoints presented at Week 16 include:
- Key major secondary endpoints:
  - Mean percent improvements from baseline in BSA and PASI
  - Proportion of participants achieving IGA 0
- Special site endpoints:
  - Proportions of participants achieving ss-IGA 0, f-IGA 0, i-IGA 0, and sPGA-G 0



Key Takeaways

- **Guselkumab is highly effective in participants with low BSA, moderate plaque psoriasis with ≥1 special sites involvement through Week 16**
- **The majority of participants achieved complete special site clearance after just 3 doses of guselkumab, substantiating its effectiveness across a broad range of patients**

Results

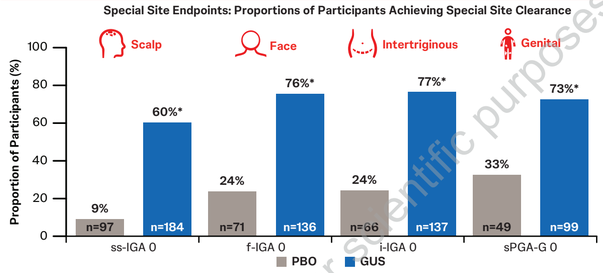
Baseline demographics and characteristics were comparable between the PBO and GUS groups

		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)
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)
Participants with ≥1 special sites PsO at baseline				
	Scalp	97 (85.8%)	184 (81.8%)	281 (83.1%)
	Face	71 (62.8%)	136 (60.4%)	207 (61.2%)
	Intertriginous	66 (58.4%)	137 (60.9%)	203 (60.1%)
	Genital	49 (43.4%)	99 (44.0%)	148 (43.8%)
Previous medication use				

Topical Agents[b] (N=338)	Phototherapy[c] (N=336)	Systemics[d] (N=336)	Advanced Orals[e] (N=336)
100%	18.5%	13.7%	4.5%

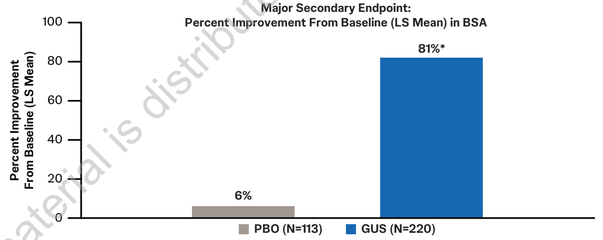
*Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]Topical, anthralin, keratolytics, and tar: [c]PUVA and UVB; [d]PUVA, methotrexate, cyclosporine, and acitretin; [e]Apremilast and deucravacitinib.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

≥60% of GUS-randomized participants achieved complete clearance of assessed special sites at Week 16



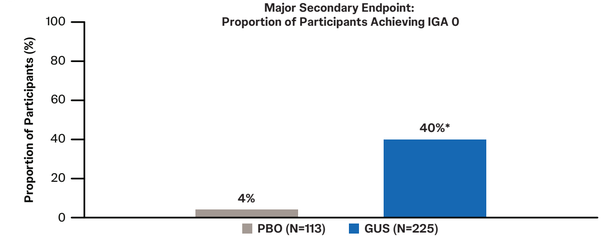
**nominal p=0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. Special site ≥1 at baseline endpoints.*

Mean % improvement in BSA for the GUS group was 81% at Week 16



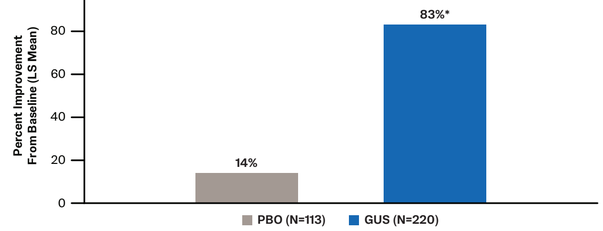
p<0.001 GUS vs PBO; p-value is based on the mixed-effect model for repeated measures (MMRM) with explanatory variables of treatment group, visit, baseline score, special site, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. When participants discontinued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

40% of GUS-randomized participants achieved complete skin clearance (IGA 0) at Week 16



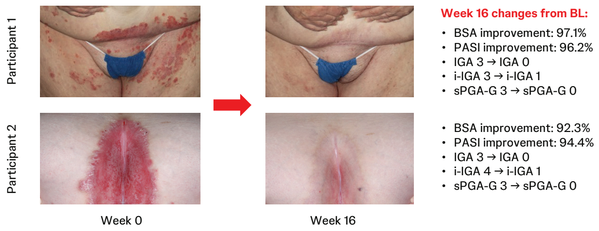
**p<0.001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel test stratified by special site (scalp, face, intertriginous, genital). Nonresponder imputation was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior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

Mean % improvement in PASI for the GUS group was 83% at Week 16



**p<0.001 GUS vs PBO; p-value is based on the MMRM with explanatory variables of treatment group, visit, baseline score, special 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 psoriasis, or use of a prohibited psoriasis treatment, zero change was assigned from that point onward. Missing data were handled by MMRM under missing at random assumption.*

GUS-randomized participants with IGA ≥3 at baseline who achieved IGA 0 at Week 16



Week 16 changes from BL:
- BSA improvement: 97.1%
- PASI improvement: 96.2%
- IGA 3 → IGA 0
- i-IGA 3 → i-IGA 1
- sPGA-G 3 → sPGA-G 0

- BSA improvement: 92.3%
- PASI improvement: 94.4%
- IGA 3 → IGA 0
- i-IGA 4 → i-IGA 1
- sPGA-G 3 → sPGA-G 0

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

	PBO N=113	GUS N=225
Safety 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%)[a]
Participants with ≥1 injection site reaction	1 (0.9%)	6 (2.7%)[b]
Infections	23 (20.4%)	50 (22.2%)
Serious infections	1 (0.9%)	0
Major adverse cardiovascular event	0	1 (0.4%)[c]

- 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. [a]One event each of upper limb fracture, renal colic, and cerebrovascular accident; [b]Of the six injections site reactions, four were mild and two were moderate, and none led to discontinuation; [c]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; **MedDRA**=Medical Dictionary for Regulatory Activities.*

PRESENTED BY: BP Glick at Fall Clinical Dermatology Conference; October 24-27, 2024; Las Vegas, NV, USA. **REFERENCES:** 1. Blauvelt A, et al. *J Psoriasis Psoriatic Arthritis*. 2023;8:100-6. 2. Gisbert NM, et al. *J Eur Acad Dermatol Venereol*. 2021;35:417-21. 3. Strober B, et al. *J Am Acad Dermatol*. 2019;82:117-22. **ACKNOWLEDGMENTS:** Medical writing support was provided by Jackie Johnson under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med*. 2022;175:1298-1304). Sponsored by Janssen Scientific Affairs, LLC, a Johnson & Johnson Company. **DISCLOSURES: JAL:** has served as a speaker for Arcutis, Eli Lilly, Incyte, and UCB; as an advisor for Arcutis and Leo Pharma; and as an investigator for Amgen, Eli Lilly, Janssen, and Takeda. **JB:** has served as an investigator, speaker, advisor/consultant for and/or received grants/honoraria from AbbVie, Amgen, Arcutis, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Galderma, Eli Lilly, Exelo, Incyte, Janssen, Johnson and Johnson, Leo Pharma, L'Oréal Group, Novartis, Pfizer, Sanofi Genzyme, Sun Pharma, Restone, UCB and Vyne. **DO:** has received consulting fees from GSK, Incyte, Janssen, Leo Pharma, Medimmune, Merck, Mirmar, Novartis, Pfizer, Regeneron, Sanofi-Genzyme, Roche, UCB. **AM:** receives honoraria or research grants from AbbVie, Acaytin, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Janssen, Novartis, Pfizer, Sanofi, Takeda, and UCB. **GY:** is a principal investigator for studies being sponsored by AbbVie, Amgen, Eli Lilly, Janssen, Mountaire, and Sanofi; has served as an advisor for AbbVie, Amgen, Arcutis, Bausch Health, Bristol Myers Squibb, Galderma, Incyte, Janssen, Johnson & Johnson, Leo Pharma, L'Oréal, Novartis, Pfizer, P&G, Sanofi, Sun Pharma, UCB and Unilever. **TA, DH, KR, and KS:** employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, Horsham, PA, USA. **JJ:** employee of Janssen Research & Development LLC, Spring House, PA, USA. **LPW:** is an employee of Janssen Inc., Toronto, ON, Canada;employees may own stock/stock options in Johnson & Johnson, of which Janssen is a subsidiary.