SPECTREM: Complete Clearance at Week 16 Across Special Sites in Guselkumab-Randomized 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)**
- **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

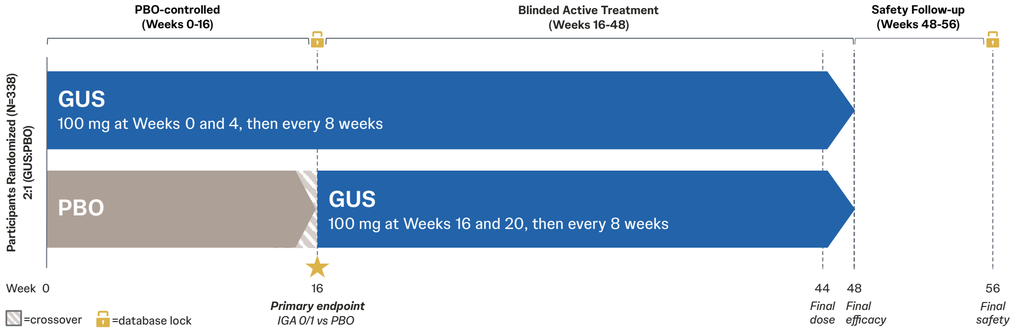
A total of 338 participants were randomized to receive GUS (N=225) or PBO (N=113)

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



GUS=Guselkumab; IGA=Investigator's Global Assessment; PBO=Placebo.

Key Takeaways

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

Results

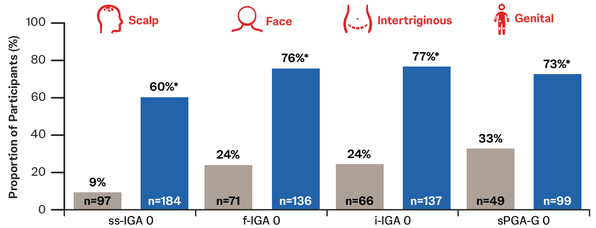
Baseline demographics and characteristics were comparable between the PBO and GUS groups

		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%

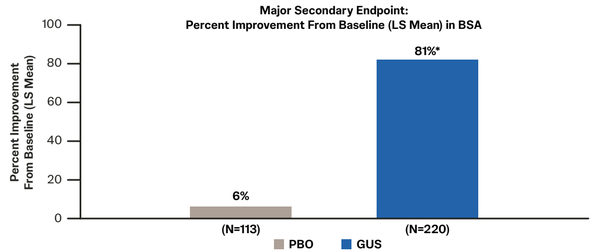
Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]Topical, anthralin, keratolytics, and tar; [c]PUVA and UVB; [d]PUVA, methotrexate, cyclosporine, and acitretin; [e]Apremilast and deucravacitinib.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

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



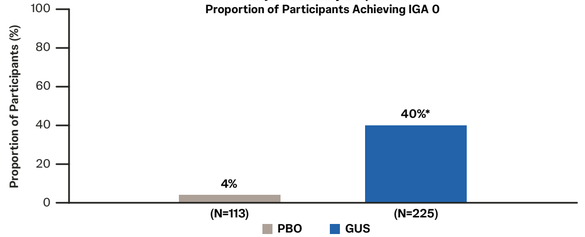
**nominal p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. Special site ≥1 at baseline endpoints. f-IGA=Facial Investigator's Global Assessment; GUS=Guselkumab; i-IGA=Intertriginous Investigator's Global Assessment; NRI=Nonresponder imputation; PBO=Placebo; PsO=Psoriasis; sPGA-G=Static Physician's Global Assessment of Genitalia; ss-IGA=Scalp-specific IGA.*

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



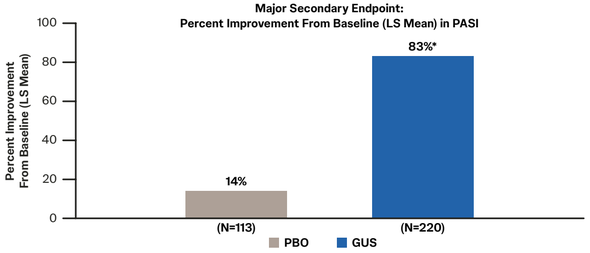
**p<0.001 GUS vs PBO; p-value is based on the MMRM with explanatory variables of treatment group, visit, baseline score, special site, an interaction term of visit with treatment group, and an interaction term of visit with baseline score. When participants discontinued study agent due to lack of efficacy, 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. BSA=Body surface area; GUS=Guselkumab; LS Mean=Least squares mean; MMRM=Mixed-effect model for repeated measures; PBO=Placebo.*

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. GUS=Guselkumab; IGA=Investigator's Global Assessment; PBO=Placebo; PsO=Psoriasis.*

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=Guselkumab; LS Mean=Least squares mean; MMRM=Mixed-effect model for repeated measures; PASI=Psoriasis Area and Severity Index; PBO=Placebo.*

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

BL=Baseline; BSA=Body surface area; IGA=Investigator's Global Assessment; i-IGA=Intertriginous IGA; PASI=Psoriasis Area and Severity Index; sPGA-G=Static Physician's Global Assessment of Genitalia.

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

Data are presented as n (%) unless otherwise noted. 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 injection-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; GUS=Guselkumab; MedDRA=Medical Dictionary for Regulatory Activities; PBO=Placebo.

PRESENTED AT: Dermatology Therapeutics Symposium (DTS); November 8-10, 2024; Austin, TX, USA. **REFERENCES:** 1. Blauvelt A, et al. *J Psoriasis Psoriatic Arthritis.* 2023;8:100-6. 2. Golbari 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;175:1298-304). Layout designing and reformatting for this encore presentation was provided by Amit Kavle of SIRO Medical Writing Pvt Ltd, Thane, Maharashtra, India. Sponsored by Janssen Scientific Affairs, LLC, a Johnson & Johnson Company. **DISCLOSURES: BPG:** is an advisory board member, consultant, speaker and/or investigator for and received honoraria or grants from Amgen, AbbVie, AstraZeneca, Almirall, Acrutis, Bausch Health/Valeant, OrthoDermatologics, Boehringer Ingelheim, Bristol Myers Squibb, Brickell Biotech, Cara Therapeutics, ChemoCentryx, Dermavant, Dermira, Eli Lilly, EPI (Novan Pharmaceuticals, Incyte, Janssen, LEO Pharma, Galderma, Nimbus Lakshmi, Inc, Novartis, Sun Pharma, Pfizer, Sanofi, Regeneron, UCB, and the CorEvitas AD, CorEvitas PSO, and PRIDE Registries; is a shareholder of Top MD, LLC. **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, Exelxis, Incyte, Janssen, Johnson & Johnson, LEO Pharma, L'Oréal Group, Novartis, Pfizer, Sanofi Genzyme, Sun Pharma, Reistone, UCB and Vyne. **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. **AM:** receives honoraria or research grants from AbbVie, Acelyrin, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Janssen, Novartis, Pfizer, Sanofi, Takeda, and UCB. **TA, KR, OC, DC, LP-W, JJ, KR,** and **PL:** employees of Janssen, a Johnson & Johnson company; employees may own stock/stock options in Johnson & Johnson. **GY:** is a principal investigator for studies being sponsored by AbbVie, Amgen, Eli Lilly, Janssen, Micelltech, 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, Proctor & Gamble, Sanofi, Sun Pharma, UCB, and Unilever. **HC-HH:** is a consultant and/or investigator and/or speaker for AbbVie, Amgen, Arcutis, ASLAN, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cutanea, Dermira, Dermavant, DS Biopharma, Eli Lilly, Evelo Biosciences, Galderma, IGM, Incyte, Janssen, LEO Pharma, Medimmune, Merck, Mitmar, Novartis, Pfizer, Regeneron, Sanofi-Aventis/Genzyme, Roche, UCB.
Previously presented at Fall Clinical Dermatology Conference (FCDC); October 24-27, 2024; Las Vegas, NV, USA.