SPECTREM: Guselkumab Demonstrates Significant 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

Objectives

To evaluate Week 16 GUS vs PBO efficacy via:

- **Special 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)

To evaluate safety in SPECTREM participants

Methods

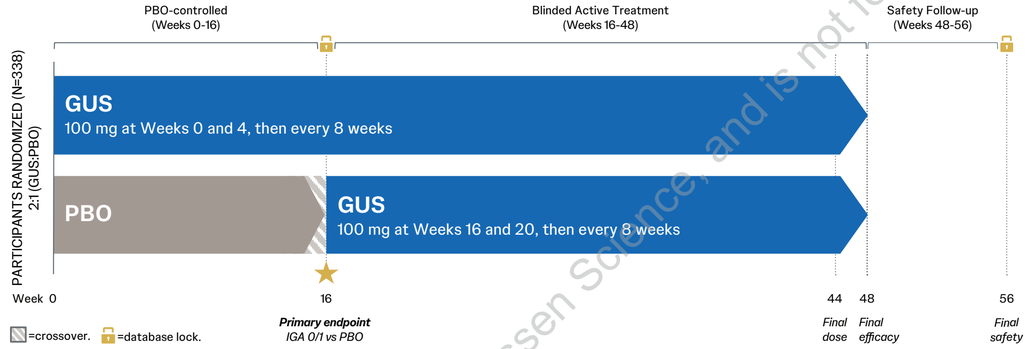
A total of 338 participants were randomized to receive GUS (N=225) or PBO (N=113)

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 included:

- Key major secondary endpoints:
  - Proportions of participants achieving ss-IGA 0/1, f-IGA 0/1, i-IGA 0/1, and sPGA-G 0/1



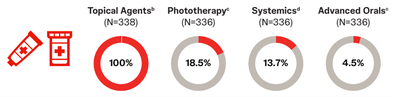
Key Takeaways

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

Results

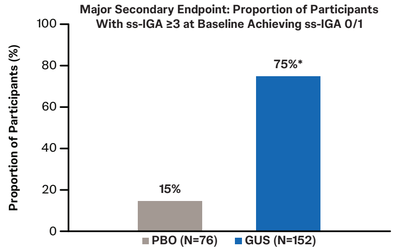
Baseline demographics and characteristics were comparable between the PBO and GUS groups

		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	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				



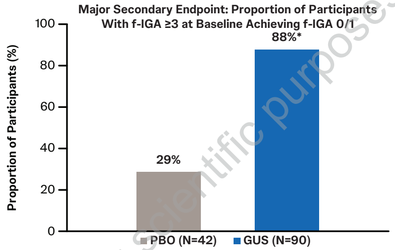
Data shown are mean (SD), unless otherwise indicated. [a]*One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4.* [b]*Inclusion criteria deviation.* [c]*Topical, anthralin, keratolytics, and tar;* [d]*PUVA and UVB;* [e]*PUVA, methotrexate, cyclosporine, and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

75% of GUS-randomized participants achieved ss-IGA 0/1 at Week 16



**p<0.001 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.*

88% of GUS-randomized participants achieved f-IGA 0/1 at Week 16



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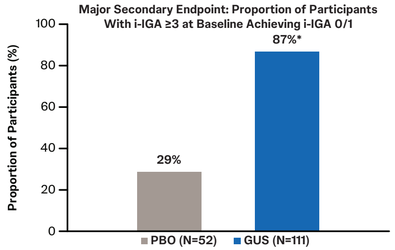
87% of GUS-randomized participants achieved i-IGA 0/1 at Week 16



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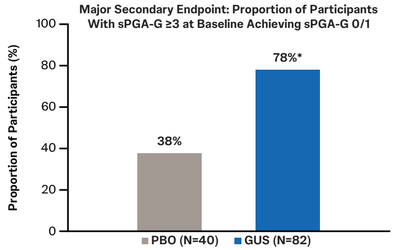
78% of GUS-randomized participants achieved sPGA-G 0/1 at Week 16



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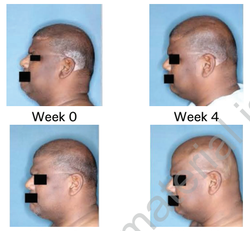
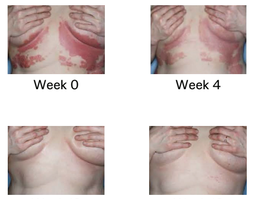
GUS-randomized participant with ss-IGA ≥3 at baseline who achieved ss-IGA 0/1 at Week 16

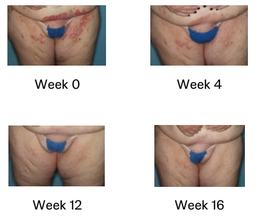


GUS-randomized participant with f-IGA ≥3 at baseline who achieved f-IGA 0/1 at Week 16

GUS-randomized participant with i-IGA ≥3 at baseline who achieved i-IGA 0/1 at Week 16



GUS-randomized participant with sPGA-G ≥3 at baseline who achieved sPGA-G 0/1 at Week 16



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 event of MACE was a cerebrovascular accident within the first week of enrollment; the participant had a history of prior transient ischemic attack.* ***AE****=adverse event;* ***MACE****=major adverse cardiovascular event;* ***MedDRA****=Medical Dictionary for Regulatory Activities.*

PRESENTED BY: AB Gottlieb at Fall Clinical Dermatology Conference; October 24-27, 2024; Las Vegas, NV, USA. **REFERENCES:** 1. Blauvelt A, et. al. *J Psoriasis Psoriatic Arthritis.* 2023;8:109. 2. Gelbari 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: RB:** is an advisory board member, consultant, speaker and/or investigator for and received honoraria and/or grants from AbbVie, Alumis, Arcutis, Amgen, Bausch Health, Boston, BMS/Celgene, Dermavant, Eli Lilly, Janssen, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, UCB, VentyxBio, and Xencor; and an employee and shareholder of Innovaderm Research. **JGZ:** has nothing to declare. **KBG:** received research/grant support from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Novartis, and UCB and honoraria for consultation from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Janssen, Novartis, and UCB. **ABG:** has received research funding and/or receives research/educational grants from Bristol Myers Squibb, Highlights Therapeutics, Janssen, and UCB (all paid to Mount Sinai School of Medicine) and has received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Asztres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA). **JK:** is a consultant and/or has received honoraria from: AbbVie, Aclaris, Allergan, Almirall, Amgen, Arena, Aristea, Asana, Aurigene, Biogen, Boehringer Ingelheim, Bristol Squibb, Eli Lilly, Escalier, Galapagos, Janssen, MoonLake, Ninbus, Novartis, Pfizer, Sanofi, Sienna, Sun, Target-Derm, UCB, Valeant, Ventyx. **JM:** is a consultant and/or investigator for AbbVie, Amgen, Astra Zeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte, Janssen, Leo Pharma, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **TA, DC, OC, and OS:** employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, Horsham, PA, USA; **JJ:** employee of Janssen Research & Development LLC, Spring House, PA, USA; employees may own stock/stock options in Johnson & Johnson, of which Janssen is a subsidiary.