SPECTREM: Guselkumab Demonstrates Consistent Significant Clearance at Week 16 Across the Full Range of Low Body Surface Area, Moderate Psoriasis with Special Sites Involvement

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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 undertreatment of patients with low BSA PsO involving special sites

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)**

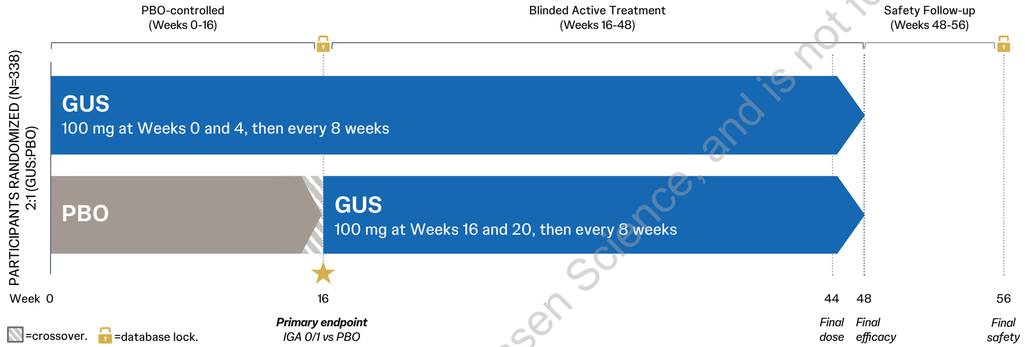
To evaluate safety in SPECTREM participants
- **Adverse events (AEs) and serious adverse events (SAEs)**

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:
- Primary endpoint: Proportion of participants achieving IGA 0/1
- Key major secondary endpoints:
  - Proportion of participants achieving PASI 90
  - Mean percent improvements from baseline in BSA and PASI



Key Takeaways

- **Guselkumab is highly effective in participants with low BSA, moderate plaque psoriasis with special sites involvement; at Week 16:**
  - **More than 70% of guselkumab-randomized participants achieved the primary endpoint (IGA 0/1)**
  - **More than 30% of guselkumab-randomized participants achieved complete skin clearance (IGA 0 and PASI 100)**
  - **Mean improvement in BSA and PASI was >80% for the guselkumab group**
- **Consistent, significant improvements across multiple clearance measures irrespective of baseline BSA support the effectiveness of guselkumab across a broad range of patients**
- **No new safety signals were identified**

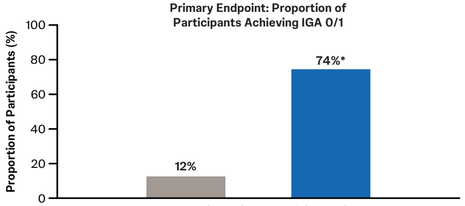
Results

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)
Previous medication use			
Topical agents[b]	113 (100%)	225 (100%)	338 (100%)
Phototherapy[c,d]	16 (14.3%)	46 (20.5%)	62 (18.5%)
Conventional systemics[c,e]	15 (13.4%)	31 (13.8%)	46 (13.7%)
Advanced orals[c,f]	4 (3.6%)	11 (4.9)%	15 (4.5%)

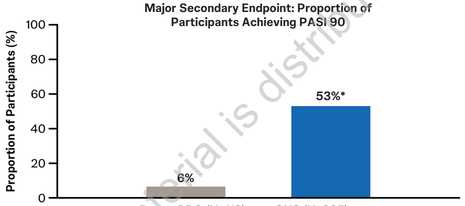
*Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]Topical, anthralin, keratolytics, tar; [c]PBO N=112, GUS N=224, Total N=336; [d]PUVA, UVB; [e]PUVA, methotrexate, cyclosporine, acitretin; [f]Apremilast, deucravacitinib. **BMI**=body mass index; **PUVA**=psoralen plus ultraviolet A; **SD**=standard deviation; **UVB**=ultraviolet B.*

A significantly greater proportion of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16



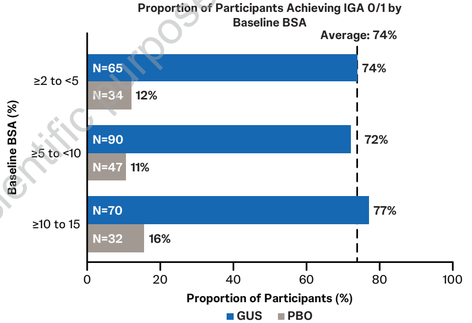
**p<0.0001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel (CMH) test stratified by special site (scalp, face, intertriginous, genital). Nonresponder imputation (NRI) was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders.*

A significantly greater proportion of GUS-randomized participants achieved PASI 90 compared to PBO-randomized participants at Week 16



**p<0.0001 GUS vs PBO; p-value is based on the CMH test stratified by special 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.*

More than 70% of GUS-randomized participants achieved IGA 0/1 at Week 16, regardless of baseline BSA



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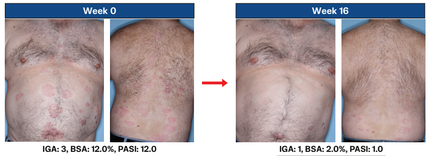
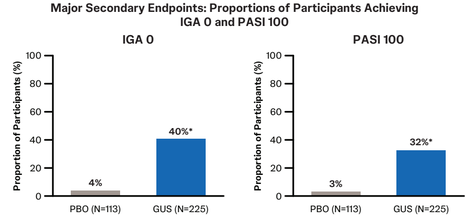
GUS-randomized participant who achieved the primary endpoint (IGA 0/1) at Week 16

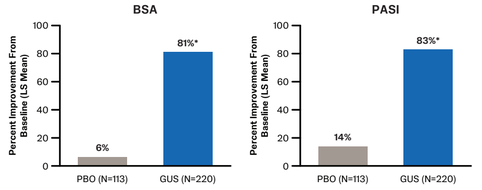


Significantly greater proportions of GUS- vs PBO-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) at Week 16



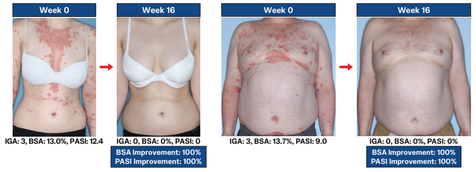
**p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by special site (scalp, face, intertriginous, genital). NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders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

The GUS group achieved significantly greater mean percent improvements in BSA and PASI compared to the PBO group 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.*

GUS-randomized participants who achieved IGA 0 and 100% improvement in BSA and PASI 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 SAE	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, 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.

PRESENTED BY: L Stein Gold at Fall Clinical Dermatology Conference, October 24-27, 2024; Las Vegas, NV, USA. **REFERENCES: 1.** Blauvelt A, et. al. *J Psoriasis Psoriatic Arthritis*. 2022;8:100-12. **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. **ACKNOWLEDGEMENTS:** Medical writing support was provided by Alyssa Cortina 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: AWA:** research investigator and/or consultant to AbbVie, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, Janssen, KHK, LEO Pharma, Modernizing Medicine, Novartis, Ortho Dermatologics, Regeneron, Sanofi, Sun Pharma, and UCB. **VG:** does not have any disclosure at this time. **RL:** has served and has received compensation in the form of grant funding and/or honoraria, as principal investigator for and is on the scientific advisory board or served as a speaker for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sun Pharma, and UCB. **MGL:** is an employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Innoyme, Janssen, Pfizer, Sanofi-Regeneron, and UCB, and is a consultant for Almirall, AltruBio Inc., Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Geilentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **KAP:** clinical research grants, honoraria, and/or consultant, scientific advisor, investigator, speaker, and/or medical officer: AbbVie, Acelyrin, Akros, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, Dermavant, Dermira, Dice Pharmaceuticals, Dice Therapeutics, Eli Lilly, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, Tarsus Pharmaceuticals, Inc., UCB, and Zai Lab Co., Ltd. **LSG:** is an investigator/advisor and/or speaker for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **BS:** served as a consultant (honoraria) and/or speaker and/or investigator for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Cara, Connect, CorEvitas Psoriasis Registry, Dermavant, Dermira, Eli Lilly, EPI, Evelo, immunic, Incyte, Janssen, LEO Pharma, Maruho, Meiji Seika, Mindera, Novartis, Ono, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma, UCB, Union, Ventyxbio, and vTv; served as Co-Scientific Director (consulting fee) of CorEvitas (formerly Corrona) Psoriasis Registry and Editor-in-Chief (honorarium) of Journal of Psoriasis and Psoriatic Arthritis. **TA, DC, and OC:** 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.