SPECTREM: Guselkumab Significantly Improves Patient Reported Outcomes at Week 16 in Participants with Low Body Surface Area Moderate Psoriasis with Special Site 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 Patient Reported Outcomes (PROs) for GUS vs PBO at Week 16 via:

- **Psoriasis Symptoms and Signs Diary (PSSD)**
- **Dermatology Life Quality Index (DLQI)**

To evaluate safety in SPECTREM participants

Methods

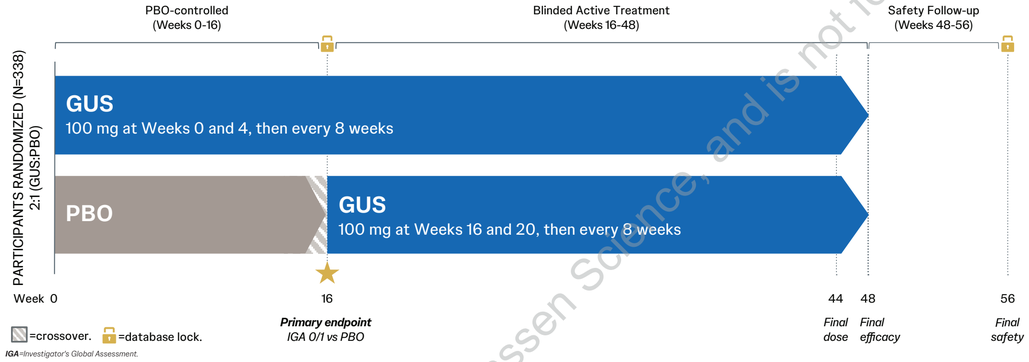
A total of 338 participants were randomized to receive GUS (N=225) or PBO (N=113)

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 change from baseline in PSSD symptom score
  - Proportion of participants achieving a ≥4-point reduction in PSSD itch score
  - Proportion of participants achieving a PSSD symptom score of 0
- Other endpoints assessed:
  - Proportion of participants achieving a DLQI score of 0/1 or 0



IGA=Investigator's Global Assessment.

Key Takeaways

- **In this low BSA moderate PsO population, quality of life as measured by the DLQI and PSSD significantly improved after just 3 doses of guselkumab**
- **Over 60% of guselkumab-treated participants were able to achieve a ≥4-point improvement in PSSD itch score from baseline**
- **Approximately 5 in 10 guselkumab-treated participants reported psoriasis had no effect on quality of life (DLQI 0/1) at Week 16**

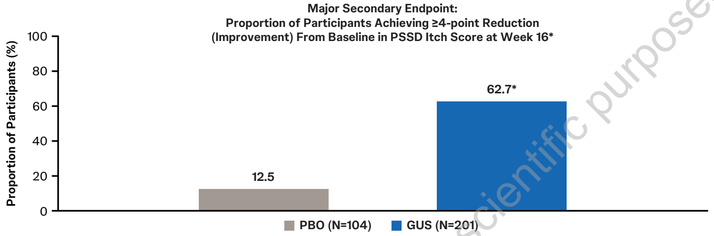
Results

Baseline demographics and 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)
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)
Never received systemic therapy[b,c]	97 (86.6%)	193 (86.2%)	290 (86.3%)
Ever used topical agents[d]	113 (100%)	225 (100%)	338 (100%)
Patient Reported Outcomes at Baseline			
PSSD symptom score (0-100)[e]	54.9 (22.0)	53.3 (23.7)	53.8 (23.2)
PSSD itch score (0-10)[e]	6.8 (2.0)	6.7 (2.2)	6.8 (2.2)
DLQI (0-30)[e]	11.9 (6.0)	11.4 (7.0)	11.5 (6.7)
DLQI score ≥10[e]	72 (64.3%)	120 (53.3%)	192 (57.0%)

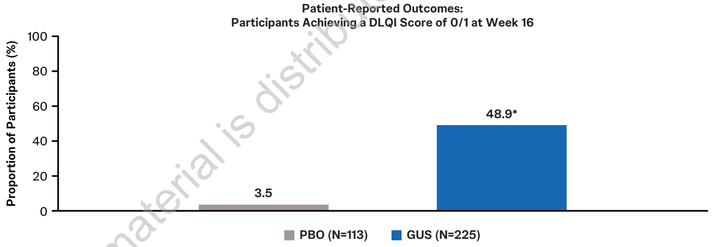
Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]PUVA, methotrexate, cyclosporine, acitretin; [c]PBO N=112, GUS N=224. Total N=336; [d]Topical agents (Topical, anthralin, keratolytics, tar); [e]PBO N=112. ***BMI****=body mass index;* ***IGA****=Investigator's Global Assessment;* ***PASI****=Psoriasis Area and Severity Index;* ***SD****=standard deviation.*

A significantly greater proportion of GUS-randomized participants achieved ≥4-point reduction (improvement) from baseline in PSSD itch score



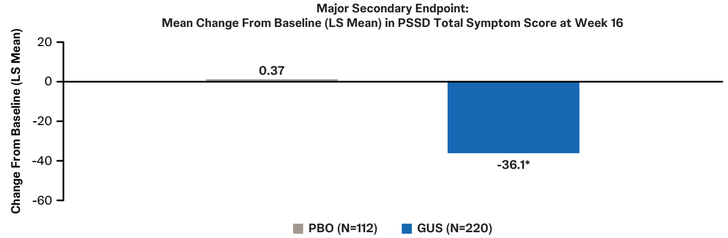
**p<0.001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel (CMH) test stratified by special site (scalp, face, intertriginous, genital). Nonresponder imputation (NRI) was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. ^Among participants with a PSSD Itch Score ≥4 at baseline.*

A significantly greater proportion of GUS-randomized participants achieved a DLQI score of 0/1 (no effect on quality of life)



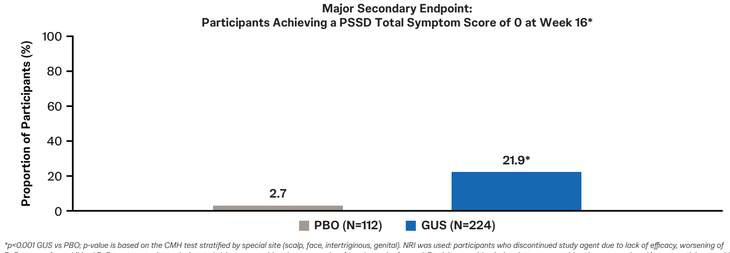
**nominal p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by special site (scalp, face, intertriginous, genital). NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered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

GUS-randomized participants achieved significantly greater mean change from baseline in the PSSD total symptom score



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. Negative change indicates an improvement, and a positive change indicates worsening of disease. 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**=least squares.*

A significantly greater proportion of GUS-randomized participants achieved a PSSD total symptom score of 0



**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. ^Among participants with a PSSD symptom score >0 at baseline.*

Safety data were consistent with the established GUS safety profile

	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, none led to discontinuation; [c]The one was a cerebrovascular accident within the first week of enrollment; the participant had a history of prior transient ischemic attack. ***AE****=adverse event.*

PRESENTED BY: J Soung at Fall Clinical Dermatology Conference; October 24-27, 2024; Las Vegas, NV, USA. **REFERENCES: 1.** Blauvelt A, et. al. *J Psoriasis Psoriatic Arthritis.* 2022;8:100-6. **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. **ACKNOWLEDGEMENTS:** Medical writing support was provided by Amy Porter 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: DNA:** has served as an investigator, speaker, or advisory board member for AbbVie, Arcutis, Amgen, Actelion, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus, Dermira, Dermavant, DICE, Eli Lilly, Galderma, Incyte, Janssen, LEO, Merck, Novartis, Pfizer, Restone, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. **VK:** Author did not report any disclosures. **JK:** declares clinical trial income from AbbVie, Alumis, Aisan, BMS, Castle, Cellex, Eli Lilly, Johnson & Johnson, Regeneron, Sanofi, Takeda, and Verasdermics; speaker honoraria from AbbVie, Amgen, Eli Lilly, Galderma, Johnson & Johnson, Regeneron, Sanofi, SUN Pharmaceuticals, and UCB; consultant income from Boehringer Ingelheim. **AOR:** has served as an advisor and/or speaker for Arcutis, Dermavent, Eli Lilly, EPI Health, Janssen, Leo, Novartis, Sciton, Sun, and UCB. He owns stock in Strathspey Crown. **MS:** has served as an investigator and/or advisor and/or speaker for AbbVie, Alumis, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Novartis, Sun Pharma, Takeda, and UCB. **MW:** has received consulting or speaker fees from AbbVie, Amgen, Arcutis, Bausch Health, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Incyte, Janssen, LEO Pharma A/S, L'Oreal, Novartis, Pfizer, Sanofi, Sun Pharma, UCB; has received grant or clinical research support from Acalyrin, AbbVie (previously Abbott), Arcus, Alumis, Apogee, Amgen, Arcutis, Asana BioSciences, AstraZeneca, Bausch Health, Bristol Myers Squibb, Celgene, Concert Pharma, Dermavent, Dermira, Dice, Eli Lilly, Evelo, Galderma, Glenmark, Incyte, Janssen, LEO Pharma A/S, Merck Frosst Canada, Moonlake, Novartis, Pfizer, Principia, PRCI, Research, Sun Pharma, Regeneron, Takeda, Timber, UCB. **JS:** has served as a speaker, consultant and/or investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Coval Biopharma, Dermavant, Eli Lilly, Janssen, KoBio Labs, LEO, National Psoriasis Foundation, Novartis, Pfizer, Regeneron, Sanofi, and UCB. **DC, OC, TJA, SR, KR, and ES:** are employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company, Horsham, PA, USA. **JJ:** employee of Janssen Research & Development LLC, Spring House, PA, USA. **NA:** is an employee of Janssen Inc., Toronto, ON, Canada; employees may own stock/stock options in Johnson & Johnson, of which Janssen is a subsidiary.