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

Brad P. Glick[1], Jennifer Beecker[2], Javier Alonso-Llamazares[3], Angela Moore[4], Theodore Alkousakis[5], Kush Shah[5], Olivia Choi[5], Daphne Chan[5], Laura Park-Wyllie[6], Jenny Jeyarajah[7], Katelyn Rowland[8], Geeta Yadav[8], H. Chih-ho Hong[9]

[1]Larkin Community Hospital, Palm Springs Campus, Miami, FL, USA; [2]JRB Research Inc., Ottawa, ON, Canada; [3]Driven Research LLC, Driven Research International LLC, Coral Gables, FL, USA; [4]Baylor University Medical Center, Dallas, TX, USA, Arlington Research Center, and Arlington Center for Dermatology, Arlington, TX, USA; [5]Johnson & Johnson, Horsham, PA, USA; [6]Johnson & Johnson, Toronto, ON, Canada; [7]Johnson & Johnson, Spring House, PA, USA; [8]FACET Dermatology, Toronto, ON, Canada; [9]University of British Columbia, Department of Dermatology and Skin Science, Vancouver, BC, Canada

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 (ie, high-impact 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 high-impact 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**
- **High-impact 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

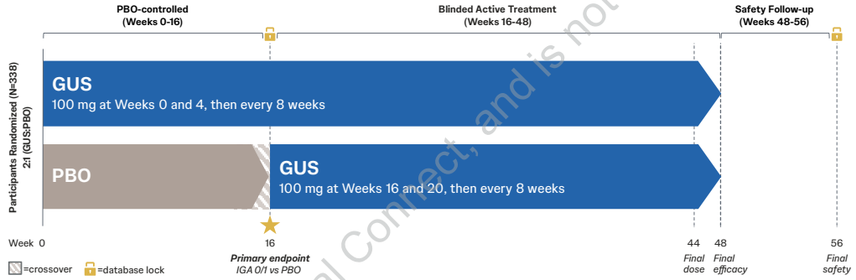
A total of 338 participants were randomized to receive GUS (n=225) or PBO (n=113)

Key Inclusion Criteria

- IGA=3
- BSA=2–15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact 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
- High-impact 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.

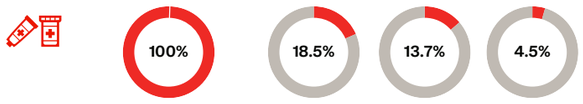
Key Takeaways

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

Results

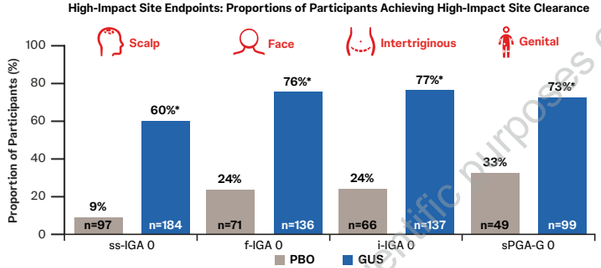
Baseline demographics and disease characteristics were comparable between the PBO and GUS groups

	PBO n=113	GUS n=225	Total N=338
Demographics			
Age, years	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)
Disease characteristics			
PsO disease duration, years	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 high-impact PsO sites 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			



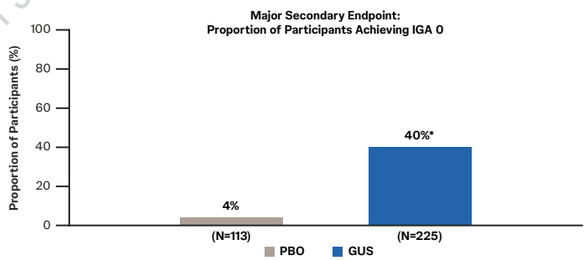
Data shown are mean (SD), unless otherwise indicated. [a]One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4. [b]Topical anthralin, keratolytics, and tar; [c]PUVA and UVB; [d]PUVA, methotrexate, cyclosporine, and acitretin; [e]Apremilast and deucravacitinib. 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 high-impact sites at Week 16



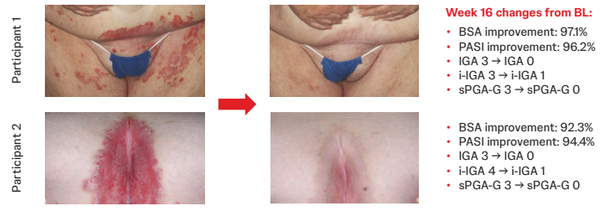
**nominal p<0.001 GUS vs PBO; p-value is based on the chi-squared test, not adjusted for baseline stratification factor. NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders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

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



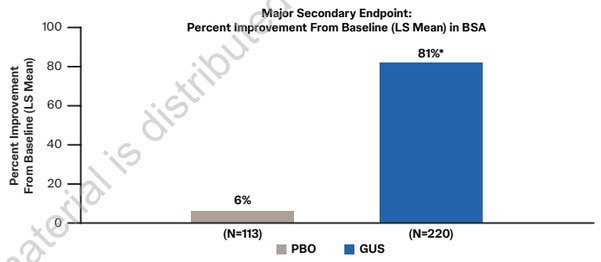
**p<0.001 GUS vs PBO; p-value is based on the Cochran-Mantel-Haenszel test stratified by high-impact site (scalp, face, intertriginous, genital). Non-responder imputation was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered non-responders from that point forward. Participants with missing data were considered non-responders. GUS=Guselkumab; IGA=Investigator's Global Assessment; PBO=Placebo; PsO=Psoriasis.*

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



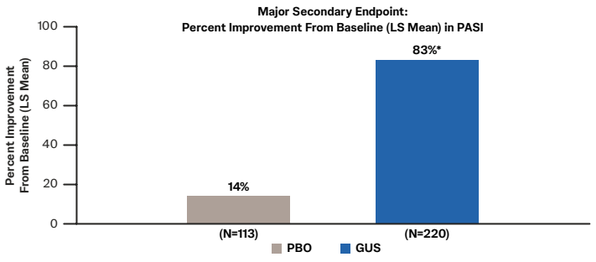
BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; i-IGA=Intertriginous IGA; PASI=Psoriasis Area and Severity Index; sPGA-G=Static Physician's Global Assessment of Genitalia.

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, high-impact 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 PsO, or use of a prohibited PsO 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; 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, high-impact 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 PsO, or use of a prohibited PsO 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; PsO=Psoriasis.*

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 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: Winter Clinical Dermatology Conference - Hawaii 2025; Waikoloa Village, HI, USA; February 14–19, 2025. **REFERENCES: 1.** Blauvelt A, et al. *J Psoriasis Psoriatic Arthritis.* 2023;8:100–8. 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). Sponsored by Johnson & Johnson. Layout design and reformatting for this encore presentation was provided by Amit Kavle of SIRO Medical Writing Pvt Ltd, Thane, Maharashtra, India. **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, Boehringer Ingelheim, Bristol Myers Squibb, Brickell Biotech, Cara Therapeutics, ChemoCentryx, Dermavant, Dermira, Eli Lilly, Elli Novan Pharmaceuticals, Galderma, Incyte, Janssen, LEO Pharma, Nimbus Lakshmi, Inc, Novartis, OrthoDermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB, and the CorEvitas AD; CorEvitas PSO, and PROSE 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, Eli Lilly, Evelo, Galderma, Incyte, Janssen, Johnson & Johnson, LEO Pharma, L'Oréal Group, Novartis, Pfizer, Reistone, Sanofi Genzyme, Sun Pharma, 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, Acellyrin, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Janssen, Novartis, Pfizer, Sanofi, Takeda, and UCB. **TA, KS, OC, DC, LP-W, JJ** and **KR:** employees of Johnson & Johnson; employees may own stock/stock options in Johnson & Johnson. **GY:** is a principal investigator for studies being sponsored by AbbVie, Amgen, Eli Lilly, Janssen, Moonlake, 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 core-steant 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, GSK, Incyte, Janssen, LEO Pharma, Medimmune, Merck, Mirinar, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, UCB. **PREVIOUSLY PRESENTED AT:** Fall Clinical Dermatology Conference; Las Vegas, NV, USA; October 24–27, 2024.