

# SPECTREM: Significant Clearance at Week 16 Across the Full Range of Guselkumab-Randomized Participants with 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  $\geq 1$  special sites
- Patients with low BSA PsO are underrepresented in clinical studies or undertreated despite being candidates for systemic treatment<sup>1-3</sup>
- SPECTREM was intentionally designed to address the undertreatment of patients with low BSA PsO involving special sites

## Objectives

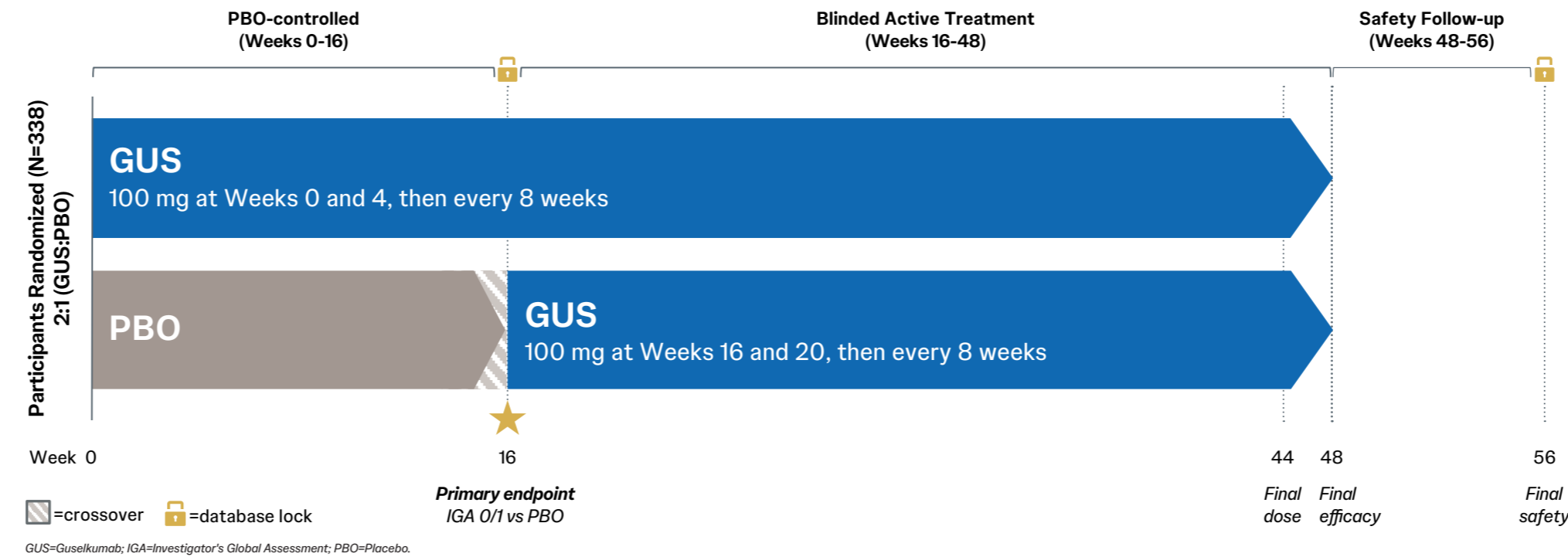
- To evaluate Week 16 GUS vs PBO efficacy via:
  - Investigator's Global Assessment (IGA)
  - Psoriasis Area and Severity Index (PASI)
  - BSA
- To evaluate safety in SPECTREM participants
  - Adverse events (AEs) and serious adverse events (SAEs)

## 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  $\geq 1$  plaque outside of special sites
  - $\geq 1$  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



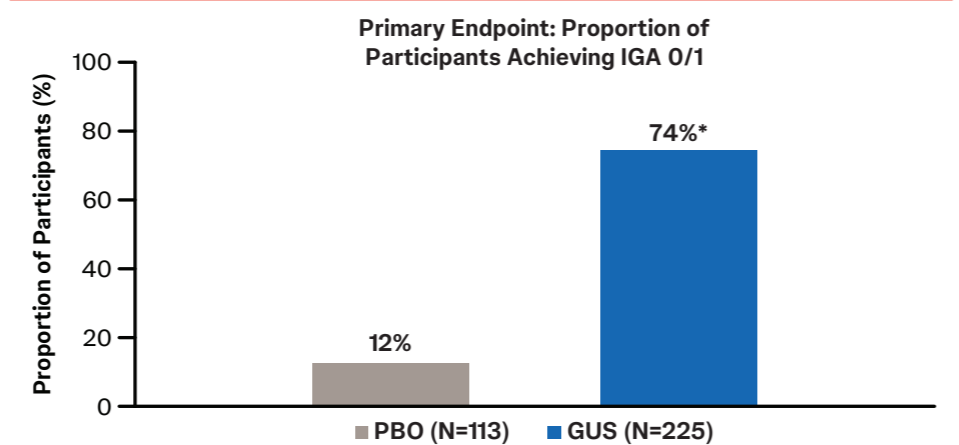
## Results

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

	PBO n=113	GUS n=225	Total N=338
<b>Demographics</b>			
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 <sup>2</sup>	31.0 (7.5)	30.9 (7.5)	30.9 (7.5)
<b>Disease characteristics</b>			
PsO disease duration, yrs	14.0 (11.9)	18.4 (14.9)	16.9 (14.1)
IGA, moderate (3)	113 (100%)	224 (99.6%) <sup>a</sup>	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)
<b>Previous medication use</b>			
Topical agents <sup>b</sup>	113 (100%)	225 (100%)	338 (100%)
Phototherapy <sup>c,d</sup>	16 (14.3%)	46 (20.5%)	62 (18.5%)
Conventional systemics <sup>e,f</sup>	15 (13.4%)	31 (13.8%)	46 (13.7%)
Advanced orals <sup>e,f</sup>	4 (3.6%)	11 (4.9%)	15 (4.5%)

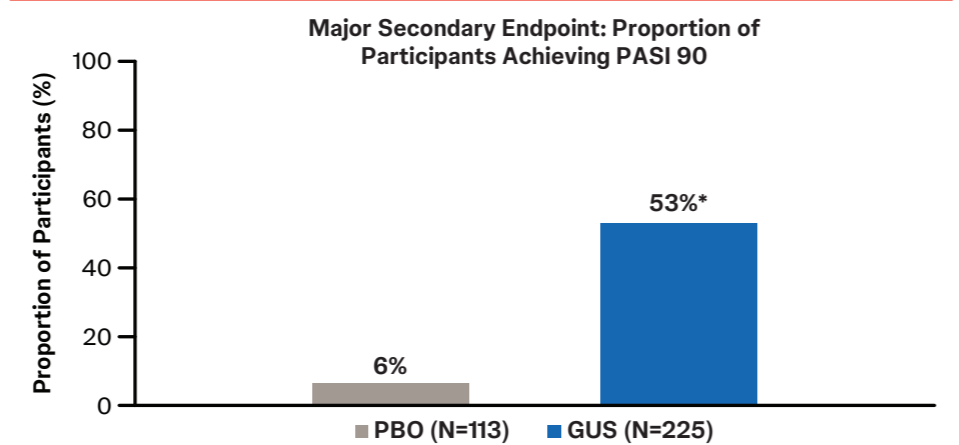
Data shown are mean (SD), unless otherwise indicated. <sup>a</sup>One GUS-randomized participant deviated from the inclusion criteria with a baseline IGA score of 4; <sup>b</sup>Topical: anthralin, keratolytics, tar; <sup>c</sup>PBO N=112, GUS N=224, Total N=336; <sup>d</sup>PUVa, UVB; <sup>e</sup>PUVa, methotrexate, cyclosporine, acitretin, Apremilast, deucravacitinib; BMI=Body mass index; BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; 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



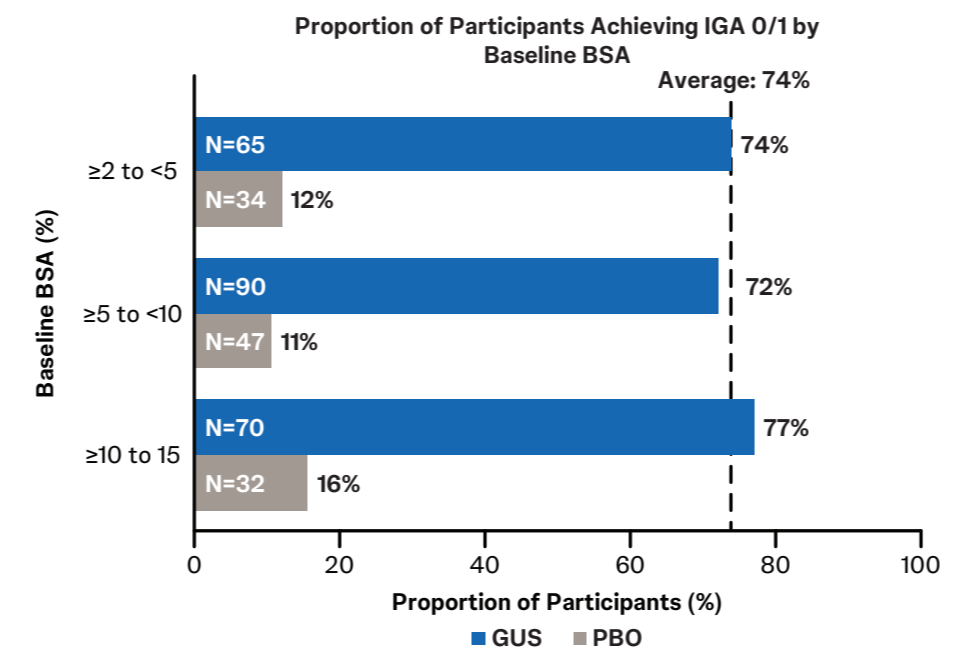
<sup>a</sup>p<0.001 GUS vs PBO; p-value is based on the CMH test stratified by special site (scalp, face, intertriginous, genital). NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered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

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



<sup>a</sup>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. CMH=Cochran-Mantel-Haenszel; GUS=Guselkumab; NRI=Nonresponder imputation; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis.

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



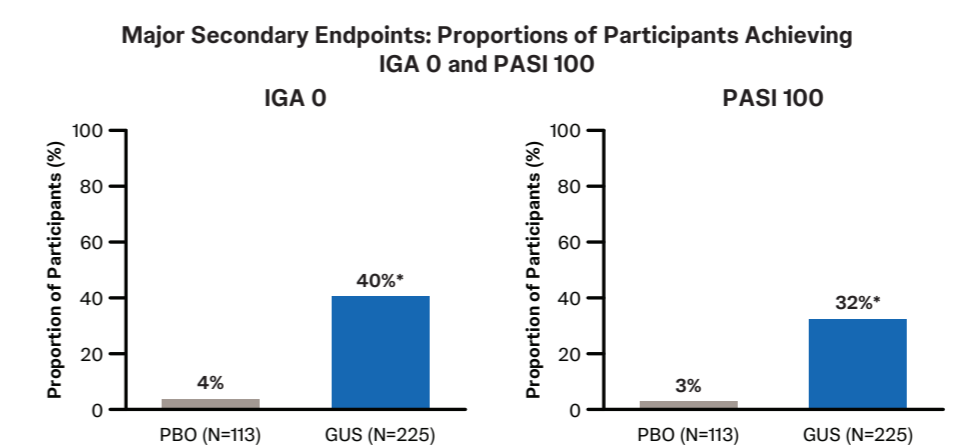
NRI was used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PsO treatment prior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered nonresponders. BSA=Body surface area; GUS=Guselkumab; IGA=Investigator's Global Assessment; NRI=Nonresponder imputation; PBO=Placebo; PsO=Psoriasis.

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



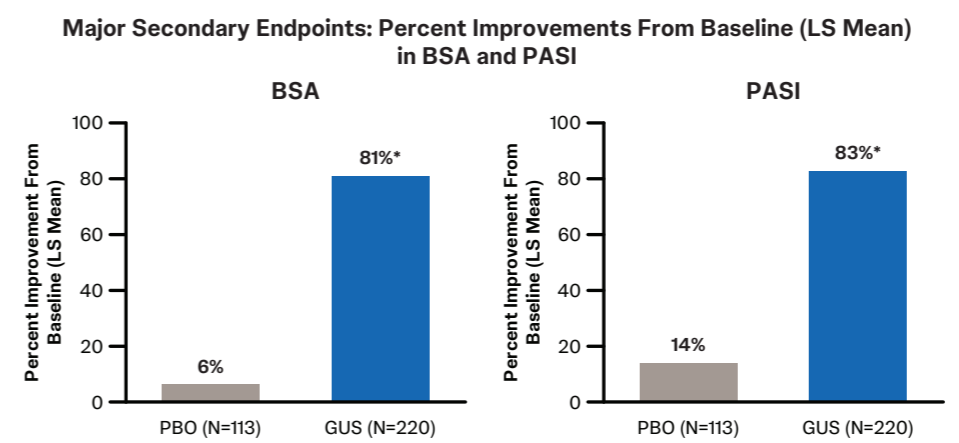
BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index.

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



<sup>a</sup>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. CMH=Cochran-Mantel-Haenszel; GUS=Guselkumab; IGA=Investigator's Global Assessment; NRI=Nonresponder imputation; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis.

The GUS group achieved significantly greater mean percent improvements in BSA and PASI compared to the PBO group at Week 16



<sup>a</sup>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; PASI=Psoriasis Area and Severity Index; PBO=Placebo.

## Key Takeaways

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

GUS-randomized participants who achieved IGA 0 and 100% improvement in BSA and PASI at Week 16



BSA=Body surface area; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index.

Safety data were consistent with the established safety profile of GUS, and no new safety signals were identified

	PBO N=113	GUS N=225
<b>Safety Through Week 16</b>		
Average duration of follow-up (weeks)	15.8	15.9
Participants with $\geq 1$ AE	45 (39.8%)	85 (37.8%)
Participants with $\geq 1$ AE leading to discontinuation of study agent	4 (3.5%)	0
Participants with $\geq 1$ SAE	1 (0.9%)	3 (1.3%) <sup>a</sup>
Participants with $\geq 1$ injection-site reaction	1 (0.9%)	6 (2.7%) <sup>b</sup>
Infections	23 (20.4%)	50 (22.2%)
Serious infections	1 (0.9%)	0
Major adverse cardiovascular event	0	1 (0.4%) <sup>c</sup>

- 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. <sup>a</sup>One event each of upper limb fracture, renal colic, and cerebrovascular accident; <sup>b</sup>Of the six injection-site reactions, four were mild and two were moderate, none led to discontinuation; <sup>c</sup>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; SAE=Serious adverse event.