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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IGA=3

special sites

PASI 90

genital)

include:

60

40

20

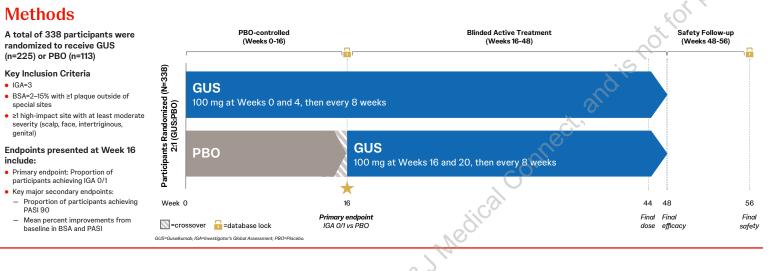
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Background

- 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 (E DA), poderate 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 treatment¹⁻³
- SPECTREM was intentionally designed to address the undertreatment of patients with low BSA PsO involving high-impact 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)



Results

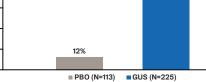
PBO and GUS groups					
		PB0 n=113	GUS n=225	Total N=338	
Demogra	aphics				
ÅÅÅ	Age, yrs	44.5 (14.9)	47.0 (14.7)	46.2 (14.8)	
	Male	57 (50.4%)	116 (51.6%)	173 (51.2%)	
	White	83 (73.5%)	166 (73.8%)	249 (73.7%)	
	BMI, kg/m ²	31.0 (7.5)	30.9 (7.5)	30.9 (7.5)	
Disease characteristics					
i	PsO disease 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%)	
lilili	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					

Baseline demographics and characteristics were comparable between the

113 (100%) 225 (100%) 338 (100%) opical agents 16 (14.3%) 46 (20.5%) 62 (18.5%) 15 (13.4%) 31 (13.8%) 46 (13,7%) ventional systemics 4 (3.6%) 11 (4.9)% 15 (4.5%)

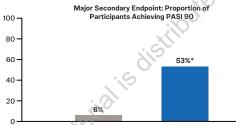
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A significantly greater proportion of GUS-randomized participants achieved the primary endpoint (IGA 0/1) compared to PBO-randomized participants at Week 16 Primary Endpoint: Proportion of 100 Participants Achieving IGA 0/1 74%* 80

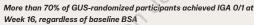


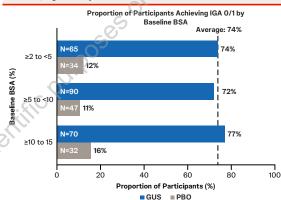
n<0.001 GUS vs PBO: n-vnlue is based on the CMH test stratified by special site (scalp, face, intertriainous, aenital). NRI was ued study agent due to lack of efficacy, wors ening of PsO, or use of a pr ders. CMH tigator's Global Asse mutation: DRO=Dlaceho: DsO=Dsoriasi

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



PBO (N=113) GUS (N=225) p<0.001 GUS vs PBC; p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). NRI was sed: participants who discontinue's study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PSC treatment rior to designated visit were considered nonseponders from that pain forward. Participants with missing data were considered sponder imputation; PASI=Psoriasis Area and Sev nesponders from ende point fo





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;

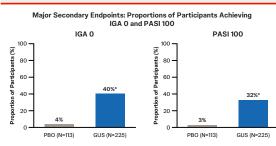
GUS-randomized participant who achieved the primary endpoint (IGA 0/1) at Week 16



BSA=Body surface area: GUS=Guselkumab: IGA=Investigator's Global Assessment: PASI=Psoriasis Area and Severity In

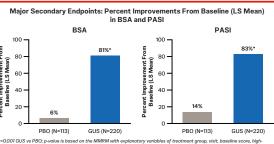
Significantly greater proportions of GUS- vs PBO-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) at Week 16

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*p<0.001 GUS vs PBO: p-value is based on the CMH test stratified by high-impact site (scalp, face, intertriginous, genital). NRI was</p> - νου στο στο στο μοταικό το υσου το υποιο στη τι στο το το τη πηρητηριας stel (scap), face, interriginous, genital). NRI wa used: participants who discontinued study agent due to lack of efficacy, worsening of PsO, or use of a prohibited PSO treatment arior to designated visit were considered nonresponders from that point forward. Participants with missing data were considered provide the state of th nszel: GUS=Guselk

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 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 particip 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 are GUS=Guselkumab; LSM=Least squares mean; MMRM=Mixed-effect model for repeated measures; PASI=Psoriasis Area and Severit

Key Takeaways



GUS is highly effective in participants with low BSA, moderate plaque PsO with high-impact 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

	PB0 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%)°

• 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. "One event each of upper limb fracture, renal colic, and cerebrovascular accident," of the six injections site reactions, four were mild and two were moderate, none led to discontinuation; "The one major adverse cardiovascula ent was a cerebrovascular accident within the first week of enrollment: the participant had a history of prior transient ischemic attack AF=Adverse event: GUS=Gusekumab: MedDRA=Medical Dictionary for Regulatory Activities: PBO=Placebo: SAF=Seriou