

SPECTREM: Guselkumab Effects on Uncontrolled Psoriatic Arthritis in Participants With Moderate, Low Body Surface Area, High-Impact Site Psoriasis Through Week 48

Joseph F. Merola¹, Richard G. Langley², Maryam Shayesteh-Alam³, Andrea Nguyen⁴, Theodore Alkousakis⁵, Sarah Ofori⁵, Elizabeth Adamson⁵, Jenny Jeyarajah⁵, Gabriela Cobos⁶, Alice B. Gottlieb¹

¹UT Southwestern Medical Center, Dallas, TX, USA; ²Dalhousie University, Halifax, Nova Scotia, Canada; ³SimcoDerm Medical and Surgical Dermatology Centre, Barrie, Ontario, Canada; ⁴First OC Dermatology, Fountain Valley, CA, USA; ⁵Johnson & Johnson, Horsham and Spring House, PA, USA; ⁶Tufts Medicine, Boston, MA, USA

Background

In patients with psoriasis (PsO), high-impact site involvement (scalp and intertriginous areas, especially the intergluteal/perianal regions) is a risk factor for psoriatic arthritis (PsA)¹⁻³

SPECTREM is a phase 3b, randomized, double-blind, placebo (PBO)-controlled study that evaluated the efficacy and safety of guselkumab (GUS) in participants with low body surface area (BSA) (2% to 15%), moderate PsO (Investigator's Global Assessment [IGA]=3) involving ≥1 high-impact site (scalp, face, intertriginous areas, or genitals)

At baseline, approximately 1 in 5 (71/338) SPECTREM participants had PsA based on a history of rheumatologist-diagnosed PsA or Psoriasis Epidemiology Screening Tool (PEST) ≥3 at screening, of which 52 participants had uncontrolled PsA based on 12-item Psoriatic Arthritis Impact of Disease questionnaire (PsAID-12) score >4.0

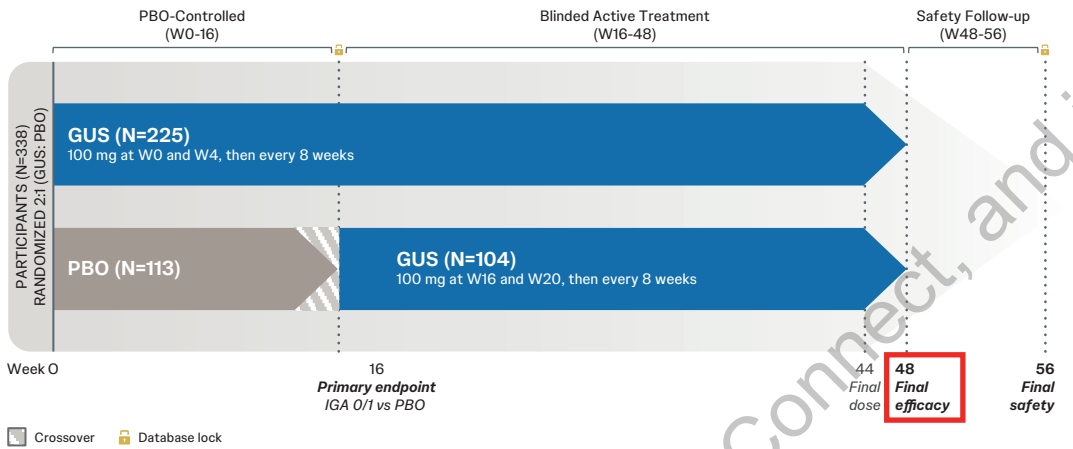
Objective

This post-hoc analysis reports PsAID-12 results through Week 48 for participants with uncontrolled PsA at baseline in SPECTREM

SPECTREM – Study Design

Key Inclusion Criteria

- IGA=3
- BSA=2-15% with ≥1 plaque outside of high-impact sites
- ≥1 high-impact site (scalp, face, intertriginous areas, genitals) with at least moderate severity (site-specific IGA/PGA ≥3)
- Prior PsO treatment: inadequate topical response or intolerance; biologic naïve; advanced oral naïve or experienced



PsA Assessments

- For participants identified to have PsA at screening (i.e., history of rheumatologist-diagnosed PsA or PEST ≥3), PsAID-12 was assessed at baseline and throughout the study
- PsAID-12 includes self-reported assessment of the physical, social, and psychological impact of PsA (score range, 0–10)^{4,5}
- A PsAID-12 score ≤4 is a patient-acceptable symptom score (PASS) and a reduction ≥3 represents minimum clinically important improvement (MCII)

Results

At baseline, 21% (71/338) of SPECTREM participants had PsA based on a history of rheumatologist-diagnosed PsA or PEST ≥3 at screening. Of these, 73% (N=52/71) had uncontrolled PsA based on PsAID-12 score >4.0

- Baseline demographics and disease characteristics were generally comparable between PsA patients diagnosed by a rheumatologist and those diagnosed by PEST screening, and between GUS and PBO treatment groups (data not shown)

Baseline Characteristics	Rheumatologist Confirmed Diagnosis of PsA (N=14)	Screening PEST Score ≥3 (N=38)
Demographics		
Age, years	49.4 (12.1)	52.1 (12.8)
Male	29%	47%
Race, White	64%	76%
BMI, kg/m ²	32.3 (6.7)	31.4 (7.2)
Disease Characteristics		
PsA disease duration, years	17.5 (9.9)	21.7 (15.3)
IGA, moderate (3)	100%	100%
BSA, %	7.1 (3.6)	7.6 (4.1)
PASI (0–72)	8.9 (3.1)	9.1 (4.1)
PsAID-12 (0-10)	6.8 (1.4)	6.3 (1.5)
Previous Medication Use		
Topical agents ^a	100%	100%
Phototherapy ^b	7%	21%
Conventional systemics ^c	21%	16%
Methotrexate	21%	11%
Advanced orals ^d	0%	5%

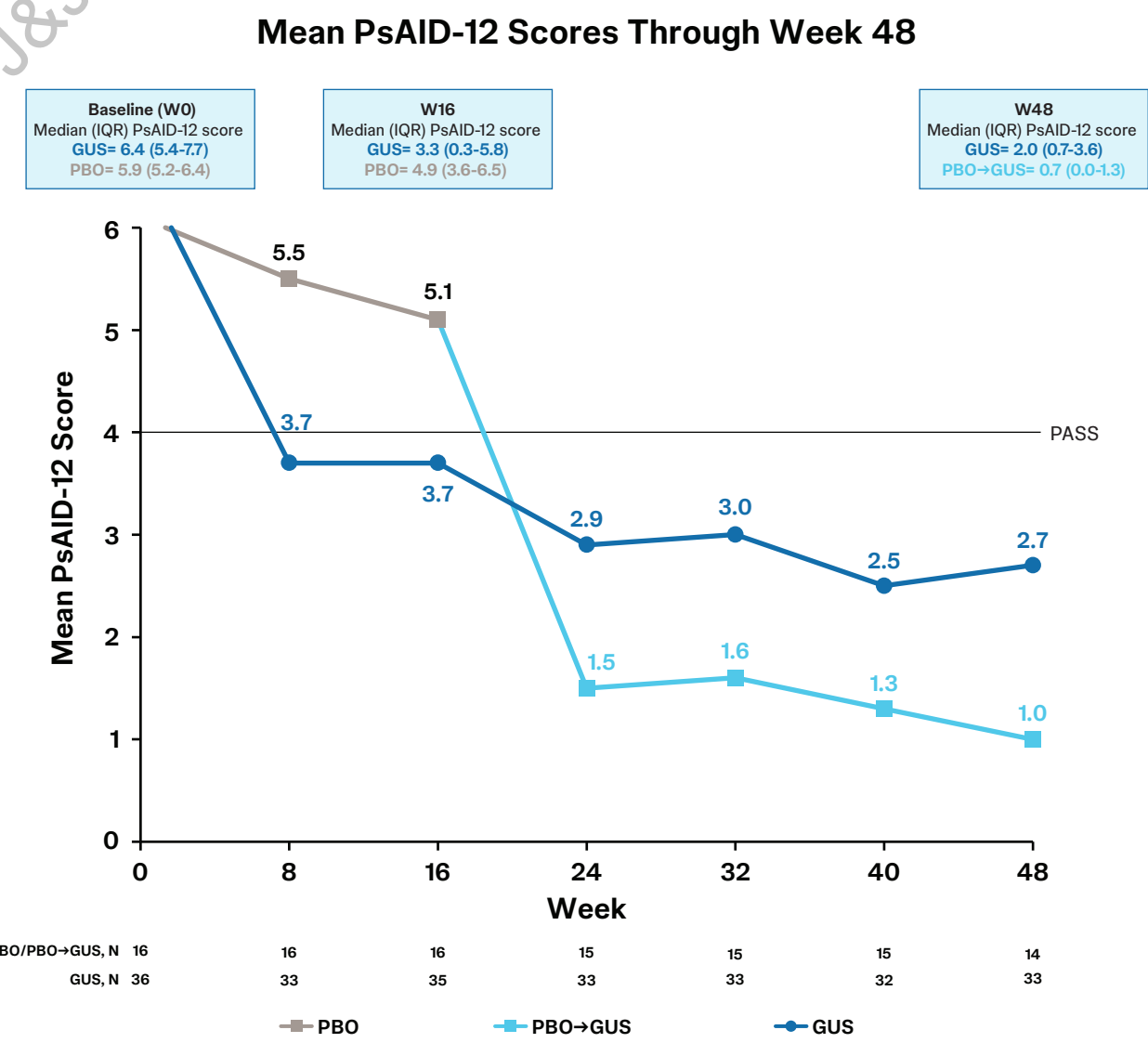
Data shown are mean (SD), unless otherwise indicated. ^aTopical: corticosteroids, keratolytics, tar. ^bPUVA, UVB. ^cPUVA, methotrexate, cyclosporine, acitretin. ^dApremilast, deucravacitinib.

BMI=body mass index; PASI=Psoriasis Area Severity Index; PUVA=psoralen plus ultraviolet A; SD=standard deviation; UVB=ultraviolet B.

Photographic skin clearance journey of a GUS-randomized participant with scalp psoriasis (baseline to Week 48)

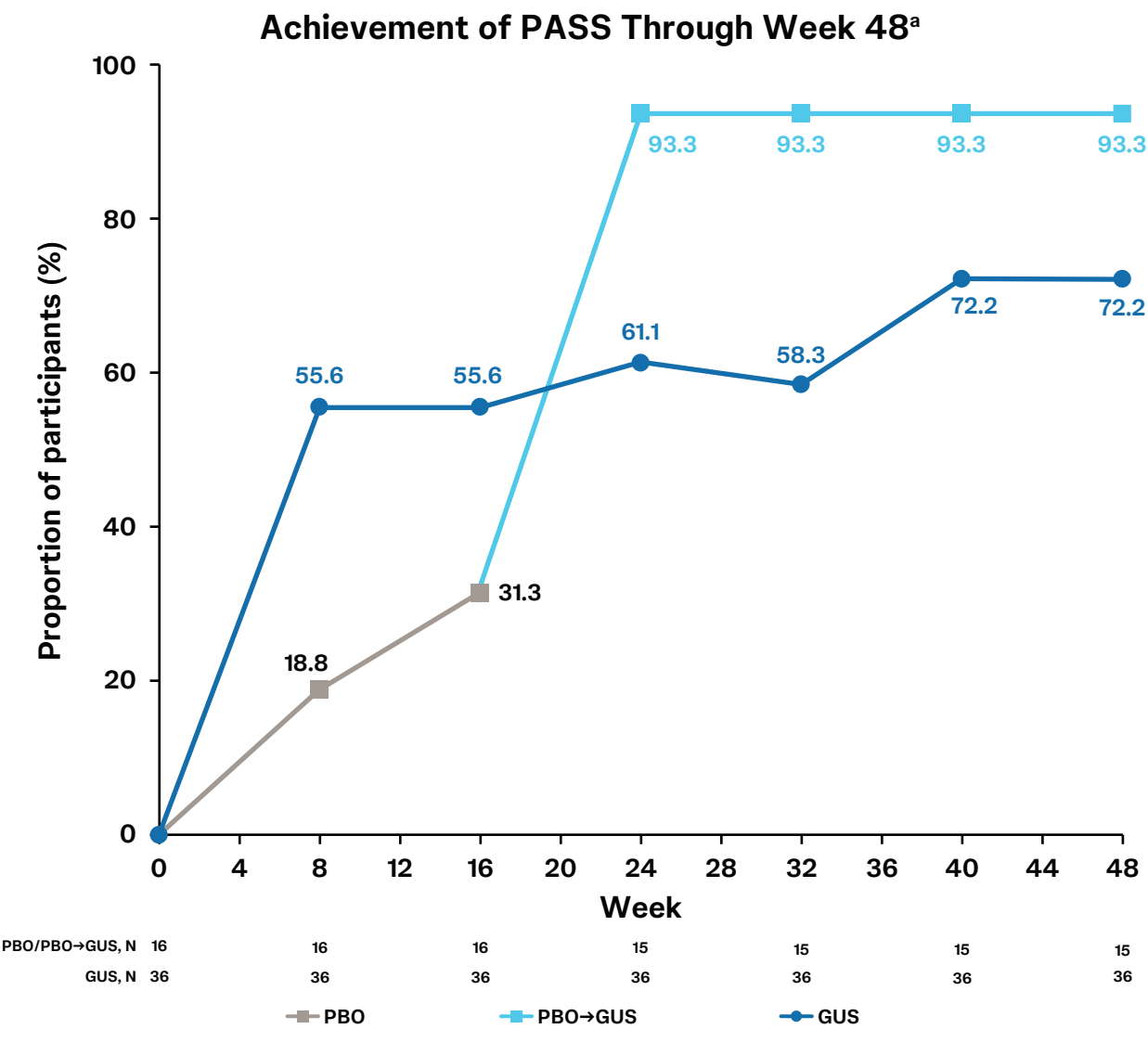


Mean PsAID-12 scores improved in the GUS-randomized group and after crossover to GUS in the PBO-randomized group, and were maintained through W48



Full Analysis Set: PsAID-12 was only assessed for participants with a history of rheumatologist-diagnosed PsA or PEST ≥3 at screening. For participants who were randomized to PBO at W0, only those participants who crossed over to GUS at or after Week 16 were included in the PBO→GUS group.

At Week 48, more than 70% of GUS-treated participants with uncontrolled PsA at baseline achieved PASS (PsAID-12 score ≤4.0)



*Full Analysis Set: participants with a screening PEST Score ≥3 or rheumatologist confirmed diagnosis of PsA and baseline PsAID-12≥4 were included in this post-hoc analysis. After applying the ICE strategy, missing data were imputed as not having achieved this endpoint. For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included.