Efficacy and Safety of Guselkumab in Participants With Active Psoriatic Arthritis and Inadequate Response and/or Intolerance to One Prior Tumor Necrosis Factor Inhibitor

Alice B. Gottlieb[1], Philip J. Mease[2,3], Alexis Ogdie[4], Christopher T. Ritchlin[5], Jose U. Scher[6], Kimberly Parnell Lafferty[7], Soumya D. Chakravarty[7,8], Yanli Wang[9], Yevgeniy Krol[7], Stacey Fitch[7], Joseph F. Merola[10]

[1]UT Southwestern Medical Center, Department of Dermatology, Dallas, TX, USA; [2]Providence Swedish Medical Center, Rheumatology Research, Seattle, WA, USA; [3]University of Washington School of Medicine, Seattle, WA, USA; [4]University of Pennsylvania School of Medicine, Philadelphia, PA, USA; [5]University of Rochester Medical Center, Rochester, NY, USA; [6]New York University School of Medicine, New York, NY, USA; [7]Johnson & Johnson, Horsham, PA, USA; [8]Drexel University College of Medicine, Philadelphia, PA, USA; [9]Johnson & Johnson, Spring House, PA, USA; [10]UT Southwestern Medical Center and O'Donnell School of Public Health, Department of Dermatology and Department of Medicine, Division of Rheumatology, Dallas, TX, USA.

Key Takeaways

- **In the SOLSTICE TNFi-IR PsA population, GUS demonstrated superior efficacy vs PBO for improving signs and symptoms of peripheral arthritis and skin PsO, including achievement of almost clear or clear skin.**
- **At W24, significantly greater proportions of pts achieved an ACR20 response in both GUS Q4W and Q8W groups vs PBO, with separation from PBO observed as early as W4**
- **Consistent treatment effect through W24 was observed with both GUS dosing regimens vs PBO with no new safety signals identified through W24**

Background

Psoriatic arthritis (PsA) is a chronic, heterogeneous, inflammatory disease that affects the joints and skin[1,2]

Guselkumab (GUS), a fully human interleukin (IL)-23p19-subunit inhibitor, demonstrated efficacy in significantly improving PsA signs and symptoms with 2 dosing regimens: 100 mg every 4 weeks (Q4W) or 100 mg at Week (W)0, W4, then Q8W (Food and Drug Administration-approved on-label dosing regimen[3]), in the pivotal Phase 3 DISCOVER-1&2 studies[4,5]

- GUS is indicated to treat moderate-to-severe plaque psoriasis (PsO), active PsA, and moderately-to-severely active Crohn's disease and ulcerative colitis[3]

Post hoc analyses of the phase 3, randomized, placebo (PBO)-controlled DISCOVER-1 study, suggested that participants (pts) who were inadequate responders (IR [inadequate efficacy/intolerance]) to a tumor necrosis factor inhibitor (TNFi) may derive incremental benefit from the more frequent Q4W dosing regimen, particularly for achieving stringent response outcomes such as ≥50%/70% improvement in the ACR response criteria (ACR50/70) and minimal disease activity (MDA)[4,6]

Objective

Report findings through W24 of SOLSTICE, an ongoing, phase 3b, randomized, double-blind, PBO-controlled study designed to further assess GUS Q4W and Q8W efficacy and safety in a dedicated pt population with active PsA who were IR to 1 prior TNFi

Methods

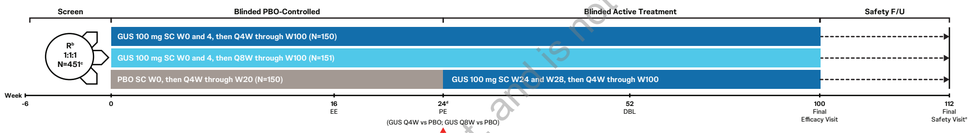
Inclusion Criteria
- ✓ Age ≥18 years
- ✓ Active PsA (≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL); CASPAR criteria met
- ✓ **Inadequate response and/or intolerance to 1 prior TNFi therapy**
- ✓ Active (≥1 PsO plaque ≥2 cm and/or nail PsO) or history of PsO

Primary Endpoint (multiplicity controlled)
- ✓ ACR20 response at W24

Major Secondary Endpoints (multiplicity controlled)
- ✓ IGA 0/1 Response (IGA 0 or 1 and ≥2-grade reduction from BL) at W24
- ✓ PASI 90 at W24
- ✓ MDA at W24

Major Secondary Endpoints (weakly controlled)*
- ✓ ACR20 at W16
- ✓ ACR50 at W24
- ✓ ACR70 at W24

Other Secondary Endpoints
- ✓ IGA 0 at W24
- ✓ PASI 100 at W24

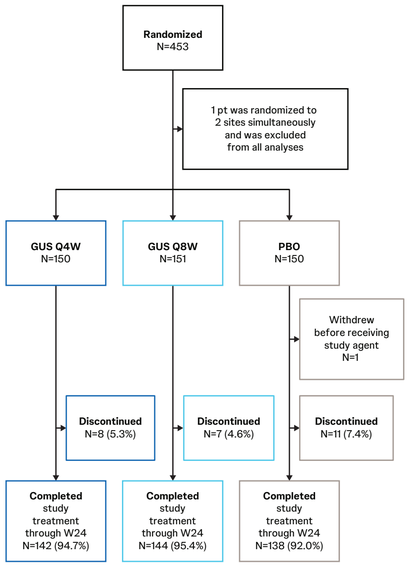


- **Efficacy analysis set:** All randomized pts; 1 pt was randomized to 2 treatment groups simultaneously and was excluded from all analyses
- **Safety analysis set:** All pts who received ≥1 administration of any study intervention; 1 pt was randomized to 2 treatment groups simultaneously and was excluded from all analyses
- After applying treatment failure rules (no change from BL or nonresponder), data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI

*Weakly controlled endpoints were not part of the sequential testing procedures but prespecified to be tested upon achieving statistical significance of the strongly controlled primary endpoints (ACR20 response at W24); p-values are not considered nominal. †Randomization was stratified by BL use of csDMARDs. ‡Total number randomized=453; the full analysis set of 451 excludes 1 pt who was double randomized. §Crossover. ¶Final safety F/U at W112 is 12W after final study agent administration. **ACR20**=≥20% in American College of Rheumatology response criteria; **BL**=baseline; **CASPAR**=CASPAR criteria for Psoriatic Arthritis; **CRP**=C-reactive protein; **csDMARD**=conventional synthetic disease-modifying antirheumatic drug; **DBL**=database lock; **EE**=early escape; **F/U**=follow-up; **IGA**=Investigator's Global Assessment of psoriasis; **MD**=Major Disruption (Ukraine and neighboring countries/territories beginning 24 February 2022); **MDA**=Minimal Disease Activity; **MI**=multiple imputation; **ND**=Natural Disaster (COVID-19 site access restrictions); **NRI**=nonresponder imputation; **PASI 90/100**=≥90% or 100% improvement in Psoriasis Area and Severity Index; **PE**=primary endpoint; **R**=randomization; **SC**=subcutaneous; **SJC**=swollen joint count; **TJC**=tender joint count.

Results

Treatment completion rates were comparable across both GUS treatment groups

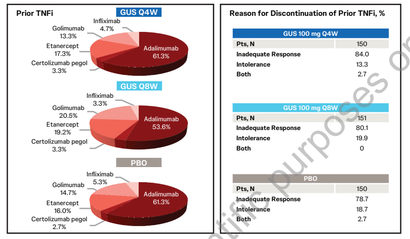


BL demographics and disease characteristics were well balanced among treatment groups

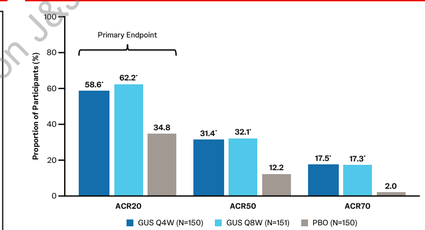
	GUS 100 mg Q4W	GUS 100 mg Q8W	PBO
Pts, N	150	151	150
Demographics			
Age, years	50.6 (13.3)	51.9 (12.9)	49.2 (12.6)
Female, n (%)	75 (50.0)	77 (51.0)	85 (56.7)
Weight,[a] kg	86.5 (20.8)	89.5 (19.8)	85.9 (21.1)
Disease Characteristics			
PsA disease duration, years	8.8 (8.3)	8.3 (7.5)	7.0 (6.6)
SJC (0-66)	10.7 (7.8)	10.3 (6.6)	10.2 (6.4)
TJC (0-68)	18.1 (12.6)	17.1 (11.2)	16.8 (11.6)
Pt Assessment of Pain [VAS; 0-10cm]	6.1 (2.0)	6.2 (2.0)	6.2 (2.0)
PtGA arthritis [VAS; 0-10cm]	6.1 (2.1)	6.2 (2.1)	6.2 (1.9)
PhGA arthritis[b] [VAS; 0-10cm]	6.5 (1.5)	6.7 (1.6)	6.5 (1.6)
HAQ-DI [0-3]	1.3 (0.6)	1.3 (0.6)	1.3 (0.6)
CRP [mg/dL]	1.2 (1.6)	1.3 (1.7)	1.4 (1.9)
IGA ≥2,[c] n (%)	106 (71.1)	105 (70.0)	111 (76.6)
BSA,[d] n (%)	12.4 (16.9)	10.7 (16.0)	9.6 (10.8)
PASI[e] [0-72]	7.29 (8.6)	6.69 (8.4)	6.05 (6.2)
FACIT-F [0-52]	28.3 (10.1)	28.2 (11.6)	27.6 (10.6)
SF-36 PCS [0-100]	34.2 (8.1)	33.6 (7.6)	33.9 (7.5)
DAPSA [HDA >28]	114 (76.0)	116 (76.8)	117 (78.0)
PASDAS[f] [0-10]	6.2 (0.9)	6.2 (1.0)	6.2 (0.9)

*Data reported as mean (SD) unless otherwise noted. †PBO N=148. ‡GUS Q4W N=149, PBO N=147. §GUS Q4W N=149, GUS Q8W N=150, PBO N=145. ¶GUS Q4W N=149, GUS Q8W N=150, PBO N=146. #GUS Q4W N=149, GUS Q8W N=150, PBO N=146. ‖GUS Q4W N=149, PBO N=147. **BSA**=body surface area; **DAPSA**=Disease Activity Index for Psoriatic Arthritis remission; nl, Low Disease Activity; >4 to ≤14, Moderate Disease Activity; >14 to ≤28, HDA; >28, **FACIT-F**=Functional Assessment of Chronic Illness Therapy-Fatigue; **HAQ-DI**=health assessment questionnaire disability index; **HDA**=High disease activity; **PASDAS**=Psoriatic Arthritis Disease Activity Score; **PhGA**=physician's global assessment of arthritis; **PtGA**=patient's global assessment of arthritis; **SD**=standard deviation; **SF-36 PCS**=36-Item Short-Form Health Survey Physical Component Summary; **VAS**=visual analog scale.

Adalimumab was the most common prior TNFi; ~80% of pts discontinued their prior TNFi due to inadequate response

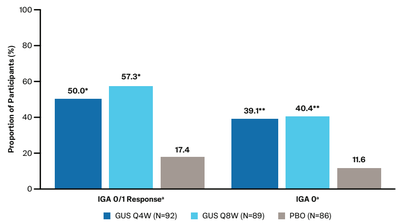


Significantly greater proportions of pts in both GUS groups vs PBO achieved ACR20/50/70 responses at W24

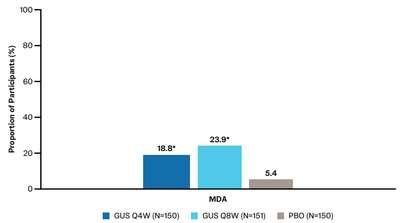


*$p<0.001$ vs PBO.

Greater proportions of GUS- vs PBO-treated pts achieved almost clear or clear skin at W24

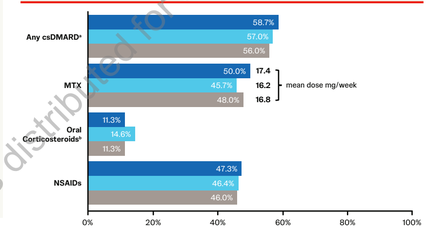


Significantly greater proportions of pts achieved MDA at W24 in both GUS dosing regimens vs PBO



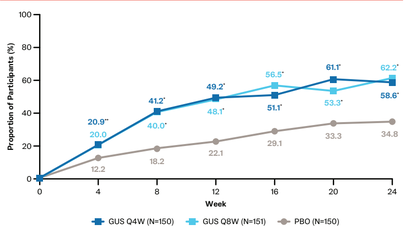
*$p<0.001$ vs PBO.

Stable doses of concomitant csDMARDs, oral corticosteroids, and NSAIDs were allowed at baseline, but not required



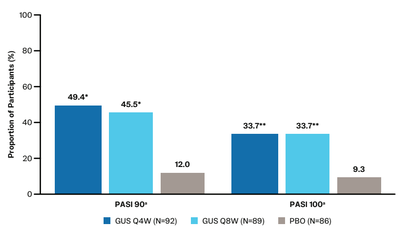
*Methotrexate, sulfasalazine, hydroxychloroquine, and leflunomide. †≤10 mg/day prednisone equivalent. **MTX**=Methotrexate, **NSAIDs**=Nonsteroidal anti-inflammatory drugs.

ACR20 response was achieved in both GUS treatment groups with separation from PBO seen as early as W4



*$p<0.001$ vs PBO, **$p=0.042$ vs PBO. ACR20 at W24 was multiplicity controlled, and ACR20 at W16 was weakly controlled; all other p-values are nominal.

Greater proportions of GUS- vs PBO-treated pts achieved almost clear or clear skin at W24



*$p<0.001$ vs PBO, **nominal $p<0.001$ vs PBO.

†Among participants with ≥3% BSA affected by PsO and ≥2 IGA at BL.

The frequencies of AEs and SAEs were similar across both GUS treatment groups and comparable to PBO

	GUS 100 mg Q4W	GUS 100 mg Q8W	PBO
Safety Analysis Set, N*	**150**	**151**	**149**
Mean weeks of follow-up	24.0	23.7	23.6
Mean number of GUS administrations	5.7	3.8	0.0
Pts with ≥1 of the following:			
AE	70 (46.7)	81 (53.6)	72 (48.3)
SAE	2 (1.3)	4 (2.6)	6 (4.0)
AE leading to discontinuation of study agent	1 (0.7)	2 (1.3)	3 (2.0)
Infections	35 (23.3)	43 (28.5)	44 (29.5)
Opportunistic infections	0	0	0
Injection site reactions	1 (0.7)	2 (1.3)	1 (0.7)

- Study remains blinded through W112
- 2 pts with serious infections; 1 malignancy[b], 1 VTE; 1 MACE[c]
- No cases of active tuberculosis, opportunistic infections, clinically important hepatic disorders, serum sickness reactions, or anaphylaxis

*Data reported as n (%) unless otherwise noted. Includes all pts who received ≥1 study agent administration. †Pts are counted only once for any given event, regardless of the number of times they actually experienced the event. ‡Non-melanoma skin cancer. §MACE resulted in death. ¶Cases are coded using Medical Dictionary for Regulatory Activities Version 27.0. **AE**=adverse event, **MACE**=Major adverse cardiovascular event (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke), **SAE**=Serious adverse event, **VTE**=Venous thromboembolism events.

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