Improvements in Patient-Reported Outcomes Through 24 Weeks of Guselkumab Treatment in Participants with Active Psoriatic Arthritis and Inadequate Response and/or Intolerance to One Prior Tumor Necrosis Factor Inhibitor

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Key Takeaways

- **In the SOLSTICE TNFi-IR population, both GUS dosing regimens demonstrated superior efficacy vs PBO in reducing fatigue, improving physical function, and enhancing overall HRQoL**
- **These findings reinforce the efficacy of GUS, irrespective of dosing regimen, in a TNFi-IR population across multiple PROs**

Background

Psoriatic arthritis (PsA), a chronic, heterogeneous, inflammatory disease affecting joints and skin, can substantially impact health-related quality of life (HRQoL) and lead to impaired physical function[1,2]

Guselkumab (GUS), a fully human interleukin (IL)-23p19-subunit inhibitor, has shown 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 Chrohn's disease and ulcerative colitis[3]

SOLSTICE is an ongoing phase 3b, multicenter, randomized, double-blind, PBO-controlled study, intended to further evaluate the efficacy of the two dosing regimens of GUS (100 mg Q4W and Q8W vs PBO) on signs and symptoms of PsA, including patient-reported outcomes (PROs) assessing physical function, fatigue, and overall HRQoL, in participants (pts) with active PsA and inadequate response (IR [inadequate efficacy/intolerance]) to 1 prior tumor necrosis factor inhibitor (TNFi)

Objective

Report findings through W24 of the ongoing SOLSTICE study, intended to further evaluate the efficacy of GUS 100 mg Q4W and Q8W vs PBO on physical function, fatigue, and overall HRQoL among TNFi-IR pts with active PsA

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 documented history of PsO

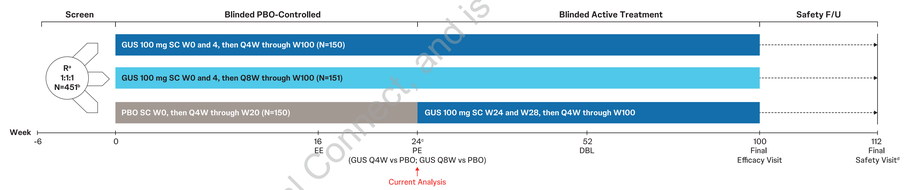
Selected Major Secondary PRO Endpoints (LSM change from BL)

- HAQ-DI (physical function)
- SF-36 PCS (HRQoL)
- FACIT-F (Fatigue)

Other Secondary Endpoints:

- HAQ-DI response (improvement ≥0.35)[a]
- FACIT-F response (improvement ≥4)[a]

*Major secondary endpoints are multiplicity controlled; p-values were based on analysis of covariance for continuous endpoints and generalized linear mixed models for binary endpoints. [a]Endpoints are prespecified but not multiplicity-controlled; p-values are considered nominal. **BL**=baseline, **CASPAR**=CASsification criteria for Psoriatic ARthritis, **CRP**=C-reactive protein, **FACIT-F**=Functional Assessment of Chronic Illness Therapy-Fatigue, **HAQ-DI**=Health Assessment Questionnaire-Disability Index, **LSM**=least squares mean, **SF-36 PCS**=36-item Short-Form Health Survey Physical Component Summary, **SJC**=swollen joint count, **TJC**=tender joint count*



- **Efficacy Analysis Set:** All randomized pts, excluding 1 randomized to 2 treatment groups
- After applying treatment failure rules (no change from BL or nonresponder), data impacted by ND/MD were not used; other missing data were imputed using MI for continuous endpoints and NRI for binary endpoints

*[a]Randomization was stratified by BL use of csDMARDs. [b]Total number randomized=453, the full analysis set of 451 excludes 1 pt who was double randomized. [c]Crossover. [d]Final safety F/U at W112 is 12W after final study agent administration. **csDMARDs**=conventional synthetic disease-modifying antirheumatic drugs, **DBL**=Database lock, **EE**=early escape, **F/U**=follow-up, **MD**=Major Disruption (Ukraine and neighboring countries/territories beginning 24 February 2022), **MI**=multiple imputation, **ND**=Natural Disaster (COVID-19 site access restrictions), **NRI**=non-responder imputation, **PE**=primary endpoint, **R**=randomization, **SC**=subcutaneous.*

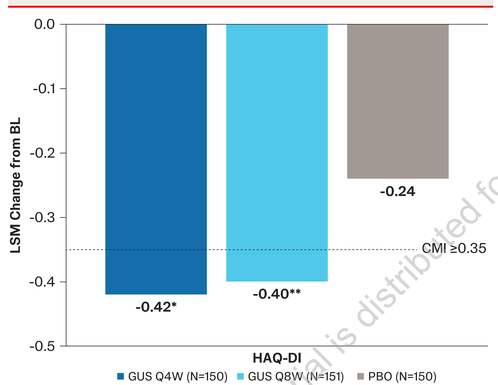
Results

Pts had moderate-to-severe impairment of physical function and fatigue at BL consistent with an active PsA population

	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	75 (50.0)	77 (51.0)	85 (56.7)
Weight,* kg	86.5 (20.8)	89.5 (19.8)	85.9 (21.1)
PROs			
HAQ-DI [0-3]	1.3 (0.6)	1.3 (0.6)	1.3 (0.6)
SF-36 PCS [0-100]	34.2 (8.1)	33.6 (7.6)	33.9 (7.5)
FACIT-F [0-52]	28.3 (10.1)	28.2 (11.6)	27.6 (10.6)
Concomitant Medications (%)			
csDMARDs	58.7	57.0	56.0
Methotrexate	50.0	45.7	48.0
Oral Corticosteroids	11.3	14.6	11.3
NSAIDs	47.3	46.4	46.0

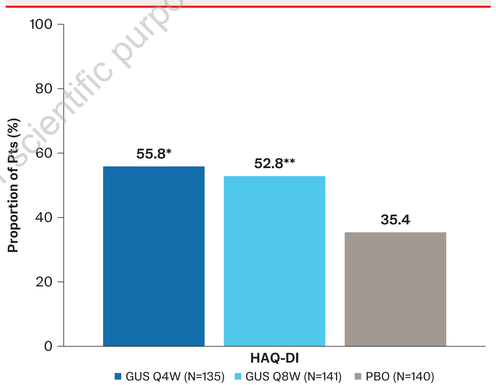
*Values are reported as n (%) or mean (SD) unless otherwise noted. *PBO N=148. **FACIT-F**=Functional Assessment of Chronic Illness Therapy-Fatigue, **NSAIDs**=Nonsteroidal anti-inflammatory drugs, **SF-36 PCS**=36-item Short-Form Health Survey Physical Component Summary*

Pts receiving GUS achieved significantly greater improvements in physical function at W24 vs PBO



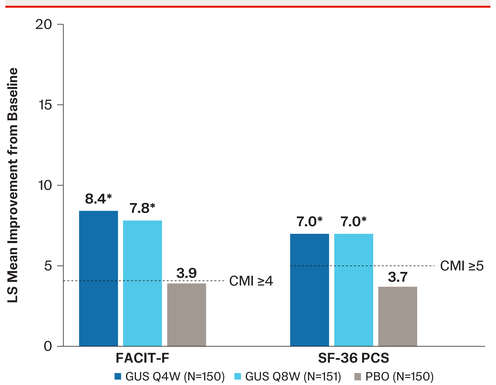
*p=0.003 vs PBO, **p=0.008 vs PBO.
CMI=clinically meaningful improvement

Greater proportions in both GUS groups achieved meaningful improvement (≥0.35) in physical function vs PBO at W24[a]



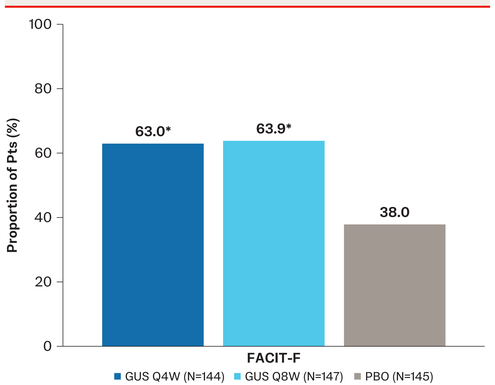
*p<0.001 vs PBO, **p=0.003 vs PBO.
[a]Among pts with a BL HAQ-DI score ≥0.35*

GUS-treated pts had significantly greater improvements from BL in fatigue and overall HRQoL compared with PBO at W24



p<0.001 vs PBO.

Greater proportions of GUS-treated pts achieved clinically meaningful improvement (≥4) in FACIT-F score vs PBO at W24



p<0.001 vs PBO.

PRESENTED AT: CCR-West; September 18-21, 2025; Huntington Beach, California, USA. **PRESENTER:** Dr. Stacey L Fitch; employee of Johnson & Johnson and owns stock in Johnson & Johnson. **REFERENCES: 1.** Gladman DD, et al. *Q J Med.* 1987;62:127–41. **2.** Ritchlin CT, et al. *J Rheumatol.* 2008;35:1434–7. **3.** Tremfya: Package insert. Horsham, PA: Janssen Biotech, Inc.; 2025. **4.** Deodhar A, et al. *Lancet.* 2020;1115–25. **5.** Mease PJ, et al. *Lancet.* 2020;395:1126–36. **ACKNOWLEDGMENTS:** Medical writing support was provided by Kristin Leppard, M.S., under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). Sponsored by Johnson & Johnson. **DISCLOSURES: ABG:** research/educational grants: Avalo Therapeutics, Bristol Myers Squibb, Johnson & Johnson, Moonlake, and UCB (all paid to Mount Sinai School of Medicine until May 1, 2025); honoraria as an advisory board member and consultant/speaker fees: Amgen, Bristol Myers Squibb, Eli Lilly. Highlights Therapeutics, Johnson & Johnson, Novartis, Sanofi, Sun Pharma, Takeda, Teva, and UCB. **JFM:** consultant and/or investigator: AbbVie, Amgen, Astra-Zeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, Moonlake, Novartis, Oruka, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **PJM:** grants: AbbVie, Acelyrin, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Novartis, and UCB; consulting fees: AbbVie, Acelyrin, Amgen, Bristol Myers Squibb, Century Therapeutics, Eli Lilly, Immagene, Johnson & Johnson, Novartis, Pfizer, Spyre, Takeda, and UCB. **CTR:** grant/research support: AbbVie, Amgen, and UCB; consulting fees: AbbVie, Amgen, Eli Lilly, Gilead, Johnson & Johnson, Novartis, Pfizer, and UCB. **JLS:** consultant: Bristol Myers Squibb, Johnson & Johnson, Pfizer and UCB; funding for investigator-initiated studies: Johnson & Johnson and Pfizer. **KPL:** employee of Johnson & Johnson and owns stock in Johnson & Johnson. **DCs:** employee of Johnson & Johnson and owns stock in Johnson & Johnson. **SDC:** employee of Johnson & Johnson and owns stock in Johnson & Johnson. **WL:** employee of Johnson & Johnson and owns stock in Johnson & Johnson. **YW:** employee of IQVIA providing statistical support (funded by Johnson & Johnson). **OC:** employee of Johnson & Johnson at the time study was conducted; owns stock in Johnson & Johnson; currently an employee of Apogee Therapeutics Inc. **YK:** employee of Johnson & Johnson and owns stock in Johnson & Johnson. **AO:** consulting fees: AbbVie, Amgen, Bristol Myers Squibb, CorEvitas, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, and UCB; advisory board fees: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, and UCB; grants: AbbVie, Pfizer, and Novartis (all to University of Pennsylvania), and Amgen (to Forward/NDB); and other funding: NIAMS, Rheumatology Research Foundation, National Psoriasis Foundation, University of Pennsylvania. Previously presented at Congress of Clinical Rheumatology (CCR) -West 2025; Huntington Beach, CA, USA; September 18-21, 2025.