Efficacy and Safety of Guselkumab in Participants With Active Psoriatic Arthritis and Inadequate Response/Intolerance to One Prior Tumor Necrosis Factor Inhibitor Through 1 Year of the SOLSTICE Study

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Key Takeaways

- **In the SOLSTICE TNFi-IR PsA population, response rate for achieving improvements in joint (ACR20/50/70) and skin (IGA 0/1; PASI 90) outcomes were sustained or numerically increased from W24–W52 among GUS-randomized pts**
- **MDA response rates numerically increased from W24–W52 in GUS-randomized pts**
- **Similar efficacy observed for both GUS Q4W and Q8W**
- **The GUS safety profile from W24–W52 was consistent with that during the PBO-controlled period; no new safety signals were identified**

Background

Guselkumab (GUS) is a fully human dual-acting[1] monoclonal antibody inhibiting the interleukin (IL)-23p19 subunit, and is approved to treat moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), and moderately-to-severely active Crohn's disease and ulcerative colitis[2]

PsA is a chronic, heterogeneous, inflammatory disease primarily affecting the joints and skin[3,4]

In SOLSTICE, a phase 3b, multicenter, randomized, placebo (PBO)-controlled study, GUS 100 mg every 4 weeks (Q4W) and every 8 weeks (Q8W) significantly improved PsA signs and symptoms through week (W) 24 in participants (pts) with inadequate response (IR; inadequate efficacy or intolerance) to 1 prior tumor necrosis factor inhibitor (TNFi)[5]

Objectives

Report efficacy and safety findings for GUS Q4W and Q8W through W52 of SOLSTICE in a dedicated TNFi-IR pt population with active PsA

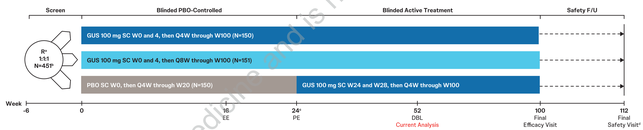
Methods

Key inclusion criteria:

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

Endpoints at W52:

- ACR20
- ACR50
- ACR70
- IGA 0/1 response: score 0 or 1 plus ≥2-grade improvement
- PASI 90
- MDA



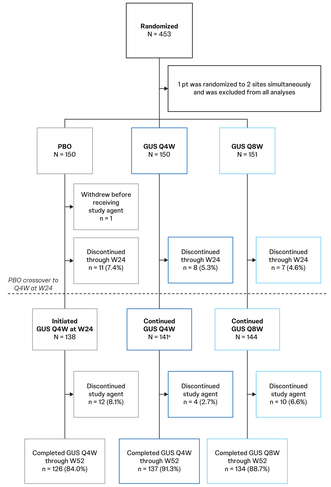
Statistical Analyses

- Pts were considered nonresponders through W24 if they increased dose/initiated csDMARDs or oral corticosteroids or initiated protocol-prohibited PsA therapies, and through W52 if they discontinued study agent for any reason other than ND/MD.
- Data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI. Response rates shown are the average proportion achieving response, over 200 MI datasets.

[1]Randomization was stratified by baseline use of csDMARDs. [2]Total number randomized=453, the full analysis set of 451 excludes 1 pt who was double randomized. [3]Crossover. [4]Final safety F/U at W112 is 12W after final study agent administration. ***ACR****=American College of Rheumatology,* ***CASPAR****=CASsification criteria for Psoriatic ARthritis,* ***CRP****=C-reactive protein,* ***csDMARDs****=conventional synthetic disease modifying antirheumatic drugs,* ***DBL****=database lock,* ***EE****=early escape,* ***F/U****=follow-up,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment of PsO,* ***MDA****=Minimal Disease Activity,* ***MD****=major disruption: involving Ukraine and neighboring countries/territories beginning 24 February 2022,* ***MI****=multiple imputation,* ***ND****=natural disaster, site closure, site access restrictions, or lockdowns due to the COVID-19 pandemic,* ***NRI****=nonresponder imputation,* ***PASI****=Psoriasis Area and Severity Index,* ***PBO****=placebo,* ***PE****=primary endpoint,* ***PsA****=psoriatic arthritis,* ***PsO****=psoriasis,* ***Pts****=participants,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***R****=randomization,* ***SC****=subcutaneous,* ***SJC****=Swollen joint count,* ***TJC****=Tender joint count,* ***TNFi****=tumor necrosis factor inhibitor,* ***W****=week.*

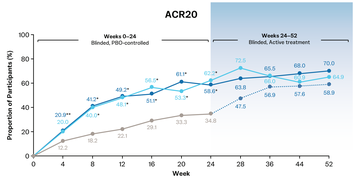
Results

Of 451 analyzed pts, 88.0% completed treatment through W52



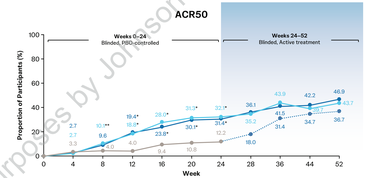
One additional pt discontinued study agent after receiving their W24 dose.* ***GUS**=guselkumab,* ***PBO****=placebo,* ***pts****=participants,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*

ACR20/50/70 response rates increased numerically from W24–W52 in GUS-randomized pts



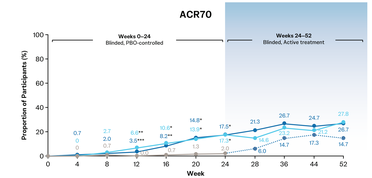
**p=0.001, †p=0.042 vs PBO*

ACR20 was weekly controlled at W16 and multiplicity-controlled at W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28–W52) used methods consistent with primary and major secondary endpoint analysis. ***ACR****=≥20% improvement in American College of Rheumatology response criteria,* ***GUS****=guselkumab,* ***PBO****=placebo,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*



**p<0.001, **p=0.039 vs PBO*

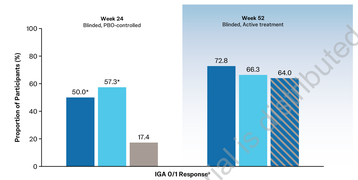
ACR50 was weekly controlled at W16 and W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28–W52) used methods consistent with primary and major secondary endpoint analysis. ***ACR****=≥50% improvement in American College of Rheumatology response criteria,* ***GUS****=guselkumab,* ***PBO****=placebo,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*



**p<0.001, †p=0.002, ‡‡p=0.021 vs PBO*

ACR70 was weekly controlled at W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28–W52) used methods consistent with primary and major secondary endpoint analysis. ***ACR****=≥70% improvement in American College of Rheumatology response criteria,* ***GUS****=guselkumab,* ***PBO****=placebo,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*

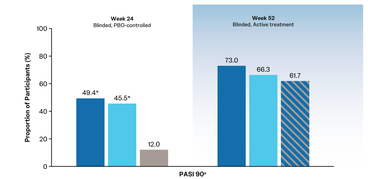
Response rates for achieving almost clear or clear skin numerically increased from W24–W52 in GUS-randomized pts



**p<0.001 vs PBO*

†Among pts with baseline BSA ≥3% and IGA ≥2 (mild). Post hoc analysis used methods consistent with primary and major secondary endpoint analysis. ***BSA****=body surface area,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment of PsO,* ***PBO****=placebo,* ***pts****=participants,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*

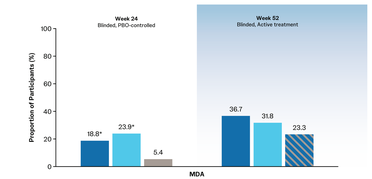
In the Q4W and Q8W groups, PASI 90 response rates indicated improvements in psoriatic skin disease from W24–W52



**p<0.001 vs PBO*

†Among pts with baseline BSA ≥3% and IGA ≥2 (mild). Post hoc analysis used methods consistent with primary and major secondary endpoint analysis. ***BSA****=body surface area,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment of PsO,* ***PASI****=Psoriasis Area and Severity Index,* ***PBO****=placebo,* ***pts****=participants,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*

MDA response rates numerically increased from W24–W52 in GUS-randomized pts



**p<0.001 vs PBO*

Post hoc analysis used methods consistent with primary and major secondary endpoint analysis. ***GUS****=guselkumab,* ***MDA****=minimal disease activity,* ***PBO****=placebo,* ***pts****=participants,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***W****=week.*

Frequencies of AEs and SAEs were similar across treatment groups

	GUS Q4W W0-24	GUS Q8W W0-24	PBO W0-24	GUS Q4W W0-52	GUS Q8W W0-52	PBO → GUS Q4W W24-52[a]
Safety Analysis Set, N[a]	150	151	149	150	151	138
Mean weeks of follow-up	24.0	23.7	23.6	50.7	50.2	27.4
Mean number of GUS administrations	5.7	3.8	0	12.1	6.6	6.7
Pts with ≥1 of the following:						
AE	70 (46.7)	81 (53.6)	72 (48.3)	97 (64.7)	101 (66.9)	64 (46.4)
Events/100 PYs	178.1	212.2	207.0	170.1	200.4	181.0
SAE	2 (1.3)	4 (2.6)	6 (4.0)	5 (3.3)	10 (6.6)	2 (1.4)
Events/100 PYs	2.9	7.2	8.8	3.4	9.6	2.8
AE leading to discontinuation of study agent	1 (0.7)	2 (1.3)	3 (2.0)	1 (0.7)	2 (1.3)	2 (1.4)
Events/100 PYs	1.4	1.4	4.4	0.7	1.4	2.8
Infections	35 (23.3)	43 (28.5)	44 (29.5)	50 (33.3)	63 (41.7)	39 (28.3)
Events/100 PYs	55.6	78.0	74.9	47.3	73.7	70.4
Opportunistic infections	0	0	0	0	0	0
Events/100 PYs	0	0	0	0	0	0
Injection site reactions	1 (0.7)	2 (1.3)	1 (0.7)	6 (4.0)	3 (2.0)	1 (0.7)
Events/100 PYs	2.8	2.9	1.5	7.5	2.8	5.5

Safety events of interest W0–W24:
- 2 x serious infections (pyelonephritis, laryngitis)
- 1 x malignancy (basal cell carcinoma)
- 1 x MACE
- 2 x VTEs (DVT and PE in same pt)
- 1 x Death (MACE pt)

Safety events of interest W24–W52:
- 1 x serious infections (cellulitis)
- 2 x malignancy (gastric cancer, colon cancer [fatal])
- 1 x death (colon cancer)

Data reported as n (%) unless otherwise noted. Includes all pts who received ≥1 study agent administration. [a]Pts are counted only once for any given event, regardless of the number of times they actually experienced the event. [b]Includes only pts who received GUS Q4W following crossover at W24. AEs are coded using Medical Dictionary for Regulatory Activities Version 27.0. ***AE****=Adverse event,* ***DVT****=deep vein thrombosis,* ***GUS****=guselkumab,* ***MACE****=Major adverse cardiovascular event (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke),* ***PBO****=placebo,* ***PE****=pulmonary embolism,* ***Pts****=participants,* ***PY****=patient-year,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks,* ***SAE****=Serious adverse event,* ***VTE****=Venous thromboembolism events,* ***W****=week.*

PRESENTED AT: The American College of Rheumatology (ACR) Convergence 2026; November 6–11, 2026; Orlando, FL, USA. **REFERENCES: 1.** Sachen KL. *Front Immunol.* 2025;16:1532852. **2.** Tremfya: Package insert. Horsham, PA: Janssen Biotech, Inc.; 2025. **3.** Gladman DD, et al. *Q J Med.* 1987;62:127–41. **4.** Ritchlin CT, et al. *J Rheumatol.* 2008;35:1434–7. **5.** Ogdie A, et al. [abstract]. *Arthritis Rheumatol.* 2025;77(suppl 9). **ACKNOWLEDGMENTS:** Medical writing support was provided by Kristin L. Leppard under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). Layout design and formatting for this encore presentation were provided by Amit Kavle of SIRO Medical Writing Pvt. Ltd., India. [Funded by Johnson & Johnson]. This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: ABG:** Research/educational grants: Bristol Myers Squibb, Johnson & Johnson, Moonlake, and UCB; all paid to Mount Sinai School of Medicine until May 1, 2025; Sub-investigator at UT SW on studies sponsored by: Bristol Myers Squibb, Johnson & Johnson, and UCB; Honoraria as an advisory board member and consultant: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Novartis, Oruka, Sanofi, Sun Pharma, Takeda, Teva, and UCB. **JFM:** Consultant and/or investigator and Grant/research support: AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, Moonlake, Novartis, Oruka, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB. **PJM:** Consulting fees: AbbVie, Amgen, Bristol Myers Squibb, Century, Cullinan, Eli Lilly, Immagene, Johnson & Johnson, Merck, Moonlake, Novartis, Pfizer, Spyre, Sun Pharma, Takeda, and UCB, Grants: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Moonlake, Novartis, Sana, Takeda, and UCB; Speaker: AbbVie, Amgen, Eli Lilly, Johnson & Johnson, Novartis, and UCB. **CTR:** Consultant: AbbVie, Amgen, Eli Lilly, Gilead, Johnson & Johnson, Novartis, Pfizer, and UCB; Grant/research support: AbbVie, Amgen, and UCB. **JUS:** Consultant: Bristol Myers Squibb, Johnson & Johnson, Novartis, Pfizer, and UCB; Grants/research support: Johnson & Johnson and Pfizer. **KPL, SDC, YK, BR,** and **SF:** Employee of Johnson & Johnson, owns stock or stock options in Johnson & Johnson. **YW:** Employee of IQVIA providing statistical support (funded by 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, Novartis (all to University of Pennsylvania), and Amgen (to Forward/NDB); Other funding: NIAMS, Rheumatology Research Foundation, National Psoriasis Foundation, and University of Pennsylvania. **PREVIOUSLY PRESENTED AT:** Rheumatology Winter Clinical Symposium (RWCS); February 11–14, 2026; Maui, HI, USA.

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