Safety of Guselkumab in Participants With Active Psoriatic Arthritis: Pooled Results From Four Phase 3, Randomized, Placebo-Controlled Trials

Atul Deodhar[1], Alexis Ogdie[2], Christopher T Ritchlin[3], Iain B McInnes[4], Soumya D Chakravarty[5,6], Elizabeth Adamson[5], Prasheen Agarwal[7], Tong Wang[7], Alice B Gottlieb[8], Philip J Mease[9,10]

[1]Division of Arthritis and Rheumatic Diseases, Oregon Health & Science University, Portland, OR, USA; [2]University of Pennsylvania School of Medicine, Philadelphia, PA, USA; [3]Department of Medicine, Allergy/Immunology and Rheumatology, University of Rochester Medical Center, Rochester, NY, USA; [4]College of Medical Veterinary and Life Sciences, University of Glasgow, Glasgow, UK; [5]Johnson & Johnson, Horsham, PA, USA; [6]Division of Rheumatology, Drexel University, Philadelphia, PA, USA; [7]Johnson & Johnson, Spring House, PA, USA; [8]Department of Dermatology, UT Southwestern Medical Center, Dallas, TX, USA; [9]Rheumatology Research, Providence Swedish Medical Center, Seattle, WA, USA; [10]University of Washington School of Medicine, Seattle, WA, USA

Scan the QR code.
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

Background

- Guselkumab (GUS) is a fully human monoclonal antibody that selectively inhibits 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[1]
- PsA is a chronic, heterogeneous, inflammatory disease primarily affecting the joints and skin[2,3]
- GUS demonstrated multidomain PsA efficacy in the phase 3, randomized, placebo (PBO)-controlled studies DISCOVER-1[4], DISCOVER-2[5], APEX[6], and SOLSTICE[7]

Objective

Evaluate the overall safety profile for GUS every 4 weeks (Q4W) and Q8W in participants with active PsA using pooled data from the PBO-controlled periods (Week [W] 0-24) in DISCOVER-1, DISCOVER-2, APEX, and SOLSTICE

Methods

- Pooled PsA phase 3/3b trials: AEs through the PBO-controlled periods (W0-24)
  - GUS 100 mg Q4W
  - GUS 100 mg at W0, 4, then Q8W
  - PBO
- Number of pts/100 PY
  - AEs
  - SAEs
  - AEs leading to study agent discontinuation
  - Infections
    - Serious infections
    - Opportunistic infections
    - Active TB
    - Candidiasis[a]
  - MACE[b]
  - Malignancies
  - Death

[a]Identified by preferred AE terms of oral candidiasis, vulvovaginal candidiasis, and skin candida. [b]Cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. ***AE***=adverse event; ***MACE***=major adverse cardiovascular event, ***SAE***=serious adverse event, ***TB***=tuberculosis.

DISCOVER-1[4]	DISCOVER-2[5]	APEX[6]	SOLSTICE[7]
• GUS Q4W N=128 • GUS Q8W N=127 • PBO N=126	• GUS Q4W N=245 • GUS Q8W N=248 • PBO N=246	• GUS Q4W N=273 • GUS Q8W N=371 • PBO N=376	• GUS Q4W N=150 • GUS Q8W N=151 • PBO N=150
Key Inclusion Criteria: • SJC ≥3; TJC ≥3; CRP ≥0.3 mg/dL • **31%: prior treatment with 1 or 2 TNFi** • **History of or active PsO (≥1 psoriatic plaque ≥2 cm or nail PsO)**	**Key Inclusion Criteria:** • SJC ≥5; TJC ≥5; CRP ≥0.6 mg/dL • **Biologic-naïve** • **History of or active PsO (≥1 psoriatic plaque ≥2 cm or nail PsO)**	**Key Inclusion Criteria:** • SJC ≥3; TJC ≥3; CRP ≥0.3 mg/dL • **≥2 erosive joints (hands/feet)** • **Biologic-naïve** • **Active PsO (≥1 psoriatic plaque ≥2 cm and/or nail PsO)**	**Key Inclusion Criteria:** • SJC ≥3; TJC ≥3; CRP ≥0.3 mg/dL • **Inadequate response (inadequate efficacy and/or intolerance) to 1 prior TNFi** • **History of or active PsO (≥1 psoriatic plaque ≥2 cm and/or nail PsO)**

CRP=C-reactive protein, ***SJC***=swollen joint count, ***TJC***=tender joint count, ***TNFi***=tumor necrosis factor inhibitor.

Key Takeaways

- **In this pooled population of pts with active PsA, including biologic-naïve and TNFi-inadequate responders, findings were consistent with the known safety profile of GUS in pts with psoriatic disease**
- **Rates of AEs were similar between the GUS and PBO groups through W24**
- **Similar safety findings were observed for both GUS Q4W and Q8W, with no apparent dose effect on AEs**

Results

BL demographics and disease characteristics were well balanced among treatment groups

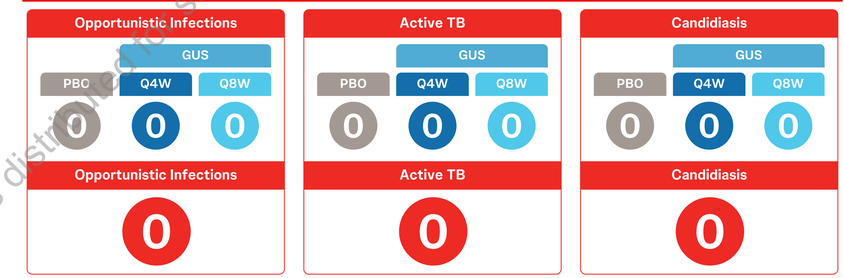
	PBO	GUS 100 mg Q4W	GUS 100 mg Q8W	Combined GUS
Pts, N	909	804	915	1719
Demographics				
Age, years	50.2 (12.6)	49.3 (12.7)	50.0 (13.0)	49.7 (12.8)
<45	302 (33.2)	282 (35.1)	317 (34.6)	599 (34.8)
≥45 and <65	484 (53.2)	429 (53.4)	475 (51.9)	904 (52.6)
≥65	123 (13.5)	93 (11.6)	123 (13.4)	216 (12.6)
Female, n (%)	449 (49.4)	368 (45.8)	438 (47.9)	806 (46.9)
Race, n (%)				
American Indian or Alaska Native	4 (0.4)	1 (0.1)	0	1 (0.1)
Asian	78 (8.6)	51 (6.3)	79 (8.6)	130 (7.6)
Black or African American	4 (0.4)	5 (0.6)	8 (0.9)	13 (0.8)
Native Hawaiian or Other Pacific Islander	0	2 (0.2)	3 (0.3)	5 (0.3)
White	817 (89.9)	744 (92.5)	822 (89.8)	1566 (91.1)
Ethnicity, n (%)				
Hispanic or Latino	33 (3.6)	22 (2.7)	27 (3.0)	49 (2.9)
Not Hispanic or Latino	873 (96.0)	782 (97.3)	882 (96.4)	1664 (96.8)
Weight, kg	84.0 (19.2)	86.0 (19.6)	84.4 (19.0)	85.1 (19.3)
≤90	587 (64.6)	499 (62.1)	585 (63.9)	1084 (63.1)
>90	319 (35.1)	304 (37.8)	329 (36.0)	633 (36.8)
Body mass index, kg/m²	29.2 (6.2)	29.5 (6.0)	29.2 (6.1)	29.4 (6.1)
Characteristics				
PsA disease duration, years	6.8 (6.6)	7.0 (7.0)	6.8 (6.9)	6.9 (6.9)
Pts with any baseline medication therapy for PsA, n (%)	804 (88.4)	697 (86.7)	793 (86.7)	1490 (86.7)
csDMARDs	604 (66.4)	526 (65.4)	612 (66.9)	1138 (66.2)
MTX	533 (58.6)	459 (57.1)	515 (56.3)	974 (56.7)
Oral Corticosteroids	161 (17.7)	126 (15.7)	151 (16.5)	277 (16.1)
NSAIDs	539 (59.3)	474 (59.0)	511 (55.8)	985 (57.3)

Data presented as mean (standard deviation) unless otherwise noted. ***csDMARDs***=*conventional synthetic disease-modifying antirheumatic drugs,* ***MTX***=*methotrexate,* ***NSAIDs***=*nonsteroidal anti-inflammatory drugs.*

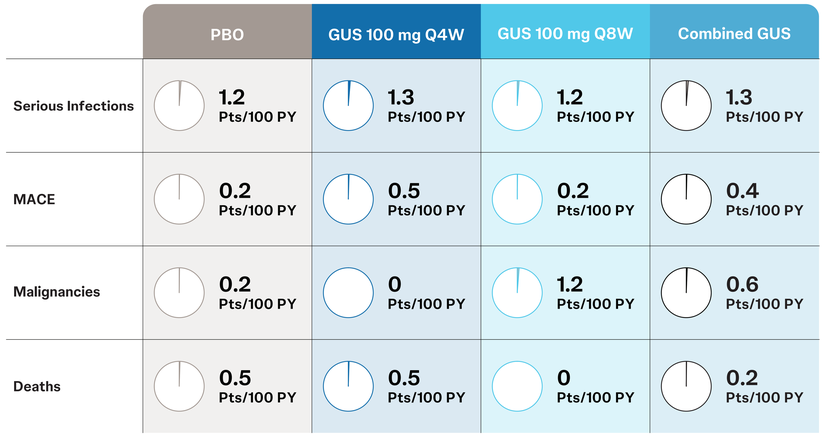
Frequencies of AEs and SAEs through W24 were similar across treatment groups

	PBO	GUS 100 mg Q4W	GUS 100 mg Q8W	Combined GUS
Safety Analysis Set, N	**907**	**803**	**914**	**1717**
Total (median) PY of follow-up	419 (0.5)	373 (0.5)	422 (0.5)	795 (0.5)
Number or pts/100 PY with ≥1				
AE	93.8	97.1	101.4	99.4
SAE	6.7	4.0	5.4	4.8
AE leading to discontinuation of study agent	2.6	3.0	3.3	3.1
Infection	47.5	42.6	49.0	46.0

There were no opportunistic infections, cases of active TB, or candidiasis through W24



Few serious infections, MACE, malignancies, or deaths occurred, and the number of pts/100 PY was similar across treatment groups[a]



[a]Only aggregate safety data are reported to maintain the blind in the ongoing SOLSTICE study as specified in the protocol. The following AEs occurred across the 4 pooled studies: serious infections (pneumonia, n=3; COVID-19, n=3; acute hepatitis B, n=1; appendicitis, n=1; diverticulitis, n=1; influenza, n=1; laryngitis, n=1; limb abscess, n=1; otitis media, n=1; cophoritis, n=1; pyelonephritis, n=1; upper respiratory tract infection, n=1); MACE (cardiovascular death, n=2; nonfatal myocardial infarction, n=1; nonfatal stroke, n=1); malignancies (basal cell carcinoma, n=1; melanoma, n=1; myeloma, n=1; prostate cancer, n=1; renal cancer, n=2); and deaths (cardiac failure, n=1; COVID-19, n=1; myocardial infarction, n=1; pneumonia, n=1).

material is distributed for scientific purposes on J&J Medical Connect, and is not for promotional use

PRESENTED AT: CCR-East; April 30–May 3, 2026; Destin, Florida, USA. **PRESENTER:** Elizabeth Adamson; employee of Johnson & Johnson and owns stock in Johnson & Johnson. **REFERENCES: 1.** TREMFYA: Package insert. Horsham, PA: Janssen Biotech, Inc.; 2025. **2.** Ritchlin CT, *J Rheumatol.* 2008;35:1434–1437. **3.** Gladman DD, et al. *Q J Med.* 1987;62:127–141. **4.** Deodhar A, et al. *Lancet.* 2020;395:1115–1125. **5.** Mease PJ, et al. *Lancet.* 2020;395:1126–1136. **6.** Mease PJ, et al. *Ann Rheum Dis.* 2025;84:1983–1994. **7.** Ogdie A, et al. *Arthritis Rheumatol.* 2026;doi: 10.1002/art.70092. **ACKNOWLEDGMENTS:** Medical writing support was provided by Maggie Paullier, PharmD under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: AD;** Consultant as an advisory board member: Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Novartis, Pfizer, and UCB; Grant/research support: Eli Lilly, Novartis, Pfizer, and UCB; Speaker fees: Eli Lilly, Johnson & Johnson, Novartis, Pfizer, and UCB. **AO:** Consultant: 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; Grant/research support: 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. **CTR:** Consultant: AbbVie, Amgen, Eli Lilly, Gilead, Johnson & Johnson, Novartis, Pfizer, and UCB; Grant/research support: AbbVie, Amgen, and UCB. **IBM:** Consultant: AbbVie, Amgen, Astra Zeneca, Bristol Myers Squibb, Cabaletta, Compugen, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi, and UCB; Grant/research support: Amgen, Astra Zeneca, Bristol Myers Squibb, Cabaletta, Dexterra, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Montai, Novartis, and UCB; Shareholder: Causeway, Cabaletta, Dexterra, Compugen; NHS GGC Board Member; and Versus Arthritis Trustee. **SDC, EA, PA, TW:** Employee: Johnson & Johnson; Shareholder: may own stock or stock options in Johnson & Johnson. **ABG:** Grant/research support: Bristol Myers Squibb, Johnson & Johnson, Moonlake, and UCB (all paid to Mount Sinai School of Medicine until May 1, 2025); Sub-investigator at UTSW on studies sponsored by: Bristol Myers Squibb, Johnson & Johnson, and UCB; Consultant Honoraria as an advisory board member: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Novartis, Oruka, Sanofi, Sun Pharma, Takeda, Teva, and UCB. **PJM:** Consultant: AbbVie, Amgen, Bristol Myers Squibb, Century, Cullinan, Eli Lilly, Inmagene, Johnson & Johnson, Merck, Moonlake, Novartis, Pfizer, Spyre, SUN Pharma, Takeda, and UCB; Grant/research support: AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Moonlake, Novartis, Sana, Takeda, and UCB; Speakers bureau: AbbVie, Amgen, Eli Lilly, Johnson & Johnson, Novartis, and UCB.