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

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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

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]

Objectives

- **Evaluate the overall safety profile for GUS every 4 weeks (Q4W) and every 8 weeks (Q8W) in participants (pts) 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, W4, 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

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)**

[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, ***GUS***=guselkumab, ***MACE***=major adverse cardiovascular event, ***PBO***=placebo, ***PsA***=psoriatic arthritis, ***pts***=participants, ***PY***=patient year, ***Q4W***=every 4 weeks, ***Q8W***=every 8 weeks, ***SAE***=serious adverse event, ***TB***=tuberculosis, ***W***=week.

CRP=C-reactive protein; ***GUS***=guselkumab, ***PBO***=placebo, ***PsO***=psoriasis, ***Q4W***=every 4 week, ***Q8W***=every 8 weeks, ***SJC***=swollen joint count, ***TJC***=tender joint count, ***TNFi***=tumor necrosis factor inhibitor.

Results

Baseline 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)

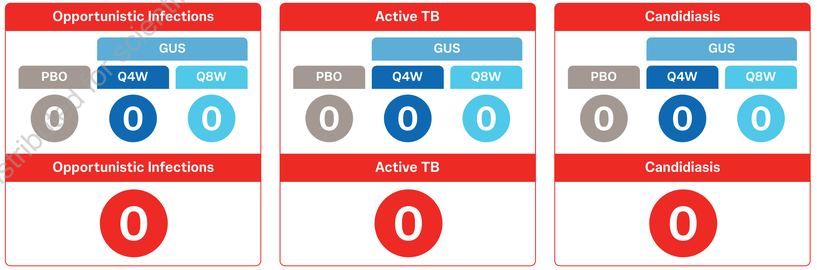
Data presented as mean (standard deviation) unless otherwise noted. ***csDMARDs***=conventional synthetic disease-modifying antirheumatic drugs, ***GUS***=guselkumab, ***MTX***=methotrexate, ***NSAIDs***=nonsteroidal anti-inflammatory drugs, ***PBO***=placebo, ***PsA***=psoriatic arthritis, ***pts***=participants, ***Q4W***=every 4 weeks, ***Q8W***=every 8 weeks.

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

AE=adverse event, ***GUS***=guselkumab, ***PBO***=placebo, ***pts***=participants, ***PY***=patient year, ***Q4W***=every 4 weeks, ***Q8W***=every 8 weeks, ***SAE***=serious adverse event, ***W***=week.

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



GUS=guselkumab, ***PBO***=placebo, ***Q4W***=every 4 weeks, ***Q8W***=every 8 week, ***TB***=tuberculosis.

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

	PBO	GUS 100 mg Q4W	GUS 100 mg Q8W	Combined GUS
Serious Infections	1.2 Pts/100 PY	1.3 Pts/100 PY	1.2 Pts/100 PY	1.3 Pts/100 PY
MACE	0.2 Pts/100 PY	0.5 Pts/100 PY	0.2 Pts/100 PY	0.4 Pts/100 PY
Malignancies	0.2 Pts/100 PY	0 Pts/100 PY	1.2 Pts/100 PY	0.6 Pts/100 PY
Deaths	0.5 Pts/100 PY	0.5 Pts/100 PY	0 Pts/100 PY	0.2 Pts/100 PY

[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; oophoritis, 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).* ***AE***=adverse event; ***COVID-19***=Coronavirus disease 2019; ***GUS***=guselkumab; ***MACE***=major adverse cardiovascular event, ***PBO***=placebo, ***pts***=participants, ***PY***=patient year, ***Q4W***=every 4 weeks, ***Q8W***=every 8 weeks.

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