TREMFYA® (guselkumab)
Treatment of Active Psoriatic Arthritis (DISCOVER-1)

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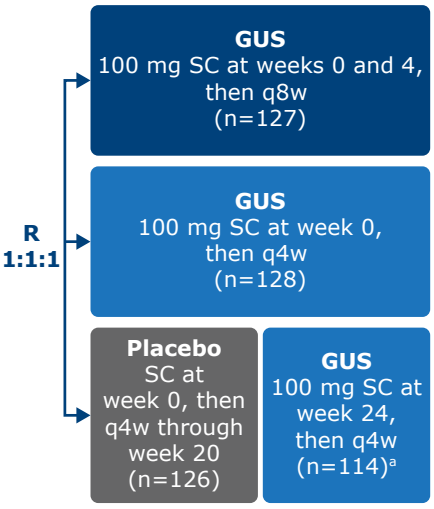
Overview[1-3]

A phase 3, randomized, multicenter, double-blind, placebo-controlled study was conducted to evaluate the efficacy and safety of GUS in adult patients with active PsA
N=381

Selected Eligibility Criteria[1,2]

- Adults with PsA ≥6 months per CASPAR criteria
- ≥3 tender and ≥3 swollen joints
- CRP ≥0.3 mg/dL
- Inadequate response or intolerance to standard therapies, including nonbiologic DMARDs, apremilast, and/or NSAIDs
- Stable doses of nonbiologic, low-dose oral corticosteroids, or NSAIDs were permitted but not required

Study Design[1,2]

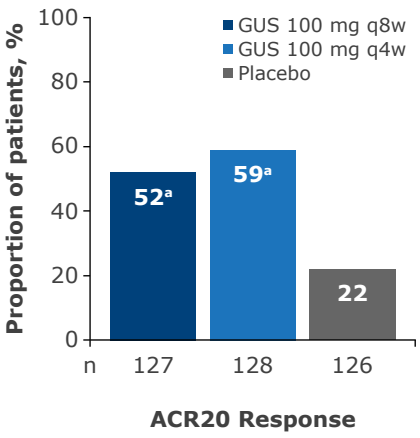


Safety follow-up: up to 60 weeks

[a]114 patients in the placebo group crossed over to GUS q4w; 12 patients received placebo only before study drug discontinuation

Primary Endpoint[1,4]

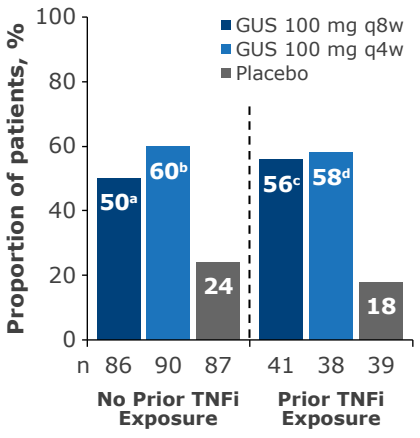
A significantly greater proportion of patients achieved an ACR20 response at week 24 in the GUS groups vs the placebo group



[a]$P<0.0001$ vs placebo.

Subgroup Analysis[1,2]

A significantly greater proportion of patients with or without prior TNFi exposure achieved an ACR20 response at week 24 in the GUS groups vs the placebo group



[a]$P=0.0005$ vs placebo; [b]$P<0.0001$ vs placebo; [c]$P=0.0004$ vs placebo; [d]$P=0.0003$ vs placebo.

Safety[1,3]

Through Week 24	GUS 100 mg q8w (n=127)	GUS 100 mg q4w (n=128)	Placebo (n=126)
Mean duration of follow-up, weeks	23.9	23.9	23.7
≥1 AE, n (%)	68 (54)	71 (55)	75 (6)
≥1 SAE, n (%)	4 (3)	0	5 (4)
Treatment discontinuation due to AEs, n (%)	3 (2)	1 (1)	3 (2)
Through Week 60	**GUS 100 mg q8w (n=127)**	**GUS 100 mg q4w (n=128)**	**Placebo to GUS 100 mg q4w (n=114)**
Mean duration of follow-up, years	1.1	1.1	0.7
All AEs, n (%)	87 (68.5)	89 (69.5)	55 (48.2)
SAEs, n (%)	8 (6.3)	4 (3.1)	4 (3.5)
Treatment discontinuation due to AEs, n (%)	5 (3.9)	1 (0.8)	3 (2.6)

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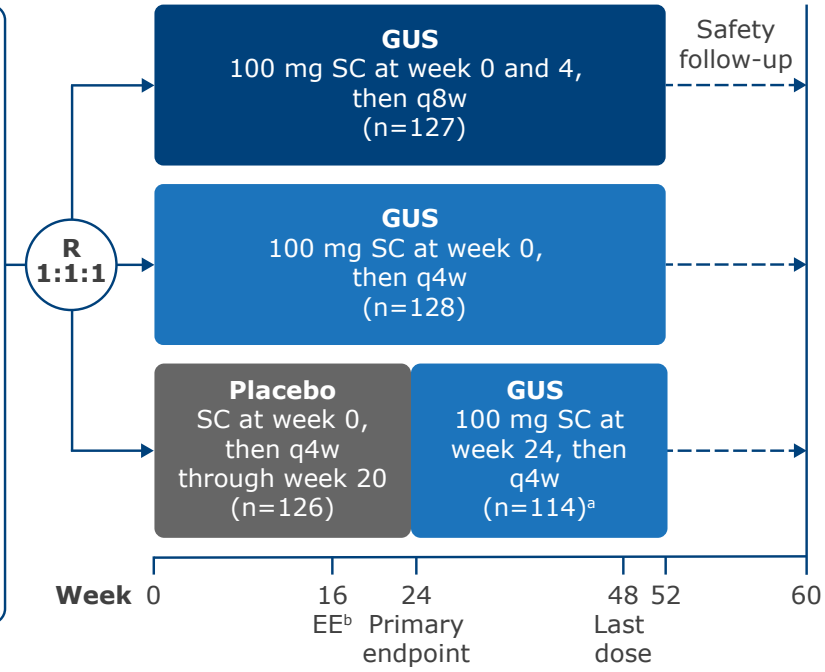
- DISCOVER-1 was a phase 3, multicenter, randomized, placebo-controlled study conducted in biologic-naïve and TNFi-experienced adult patients with active PsA despite treatment with standard therapies, including nonbiologic DMARDs, apremilast, and NSAIDs.[1-3]

Inclusion Criteria

- Age >18 years
- PsA ≥6 months per CASPAR criteria
- ≥3 tender and ≥3 swollen joints
- CRP ≥0.3 mg/dL
- History of or active plaque PsO, or nail changes consistent with PsO
- Inadequate response or intolerance to standard therapies, including nonbiologic DMARDs, apremilast, and/or NSAIDs
- Prior exposure of up to 2 TNFi (~30% of study population)
- Stable doses of nonbiologic DMARDs, low-dose oral corticosteroids, or NSAIDs were permitted but not required



[a]114 patients in the placebo group crossed over to GUS q4w; 12 patients received placebo only before study drug discontinuation
[b]Patients were eligible to initiate/increase background medications if there was <5% improvement from baseline in tender and swollen joint counts at week 16.

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Primary Endpoint[1,2]

- Proportion of patients achieving an ACR20 response at week 24

Major Secondary Endpoints[a,1,2]

- Change from baseline in HAQ-DI scores at week 24
- IGA PsO score of 0 (cleared) or 1 (minimal) and ≥2 grades of reduction from baseline at week 24
- Change from baseline in SF-36 PCS score at week 24

Uncontrolled Secondary Endpoints[b,1,2]

- Proportion of patients achieving ≥0.35 improvement from baseline in HAQ-DI scores at week 24
- Proportion of patients achieving PASI75, PASI90, and PASI100 at week 24
- Change in the DAS28-CRP at week 24
- Change from baseline in SF-36 MCS score at week 24
- MDA response at week 24

[a]Endpoints were adjusted for multiplicity as per US statistical protocol.
[b]Endpoints were not adjusted for multiplicity as per US statistical protocol.

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- Data handling rules were applied to all efficacy analyses from week 0 to week 24.[1,2]
- Patients who met treatment failure criteria (discontinued study treatment, terminated study participation, initiated or increased DMARD or oral corticosteroid use, or initiated protocol-prohibited PsA treatment) were considered nonresponders for binary endpoints and as having no improvement from baseline for continuous endpoints.[1,2]
- NRI data was derived from randomized patients who received ≥1 dose of study agent.[1,2]
- Missing data were handled as follows:[1,2]
  - Patients with missing response endpoint data through week 52 were considered nonresponders.
  - Missing continuous endpoint data due to study agent discontinuation were imputed as no change.
  - Other missing continuous endpoint data were imputed using multiple imputation.

- Baseline demographics were generally similar between the treatment groups.[1]

Summary of Select Patient Baseline Demographics[1]

Characteristic	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
Age, years, mean	48.9	47.4	49.0
Sex, n (%)			
Female	59 (46)	62 (48)	65 (52)
Male	68 (54)	66 (52)	61 (48)
PsA duration, years, mean (SD)	6.4 (5.9)	6.6 (6.3)	7.2 (7.6)
Number of swollen joints, 0-66, mean (SD)	10.9 (9.3)	8.6 (5.8)	10.1 (7.1)
Number of tender joints, 0-68, mean (SD)	20.2 (14.5)	17.7 (13.1)	19.8 (14.4)
Patient's assessment of pain, 0-10 cm VAS, mean (SD)	6.0 (2.1)	5.9 (2.0)	5.8 (2.2)
Patient's global assessment-arthritis, 0-10 cm VAS, mean (SD)	6.5 (2.0)	6.1 (2.0)	6.1 (2.2)
Physician's global assessment, 0-10 cm VAS, mean (SD)	6.2 (1.7)	6.2 (1.6)	6.3 (1.7)
HAQ-DI score, 0-3, mean (SD)	1.2 (0.6)	1.1 (0.6)	1.1 (0.6)
CRP, mg/dL, median (IQR)	0.7 (0.4-1.9)	0.6 (0.3-1.3)	0.8 (0.3-1.5)
Psoriatic BSA, 0%-100%, mean (SD)	13.1 (18.0)	15.0 (18.0)	12.0 (16.0)
IGA score of 3 or 4, n (%)	57 (45)	62 (48)	43 (34)
PASI score, 0-72, mean (SD)	8.4 (9.8)	9.5 (10.1)	7.7 (8.8)
Patients with enthesitis, n (%)	72 (57)[a]	73 (57)	77 (61)
LEI score, 1-6,[b] mean (SD)	2.7 (1.6)	3.0 (1.5)	2.8 (1.6)
Patients with dactylitis, n (%)	49 (39)	38 (30)	55 (44)
Dactylitis score, 1-60,[c] mean (SD)	8.2 (10.0)	9.4 (12.5)	6.6 (7.4)
SF-36, mean (SD)			
PCS, 0-100	34.1 (7.6)	35.9 (8.3)	33.8 (8.5)
MCS, 0-100	47.0 (11.1)	46.5 (9.8)	48.7 (9.6)

[a]The denominator for this percentage is 126 because 1 patient in this group did not have the score measured at baseline.
[b]Among patients with available LEI score at baseline (q4w group, n=73; q8w group, n=72; and placebo group, n=77).
[c]Among patients with dactylitis score at baseline (q4w group, n=38; q8w group, n=49; and placebo group, n=55).

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- Medication use at baseline were generally similar between the treatment groups.[1]

Medication Use at Baseline[1]

Characteristic	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
Previous TNFi use, n (%)	41 (32)	38 (30)	39 (31)
One previous TNFi	34 (27)	33 (26)	35 (28)
Two previous TNFi	7 (6)	5 (4)	4 (3)
Patients who did not respond to previous TNFi	15 (12)	17 (13)	12 (10)
Previous apremilast use, mean (SD)	6 (5)	2 (2)	4 (3)
Drug use at baseline			
DMARDs, n (%)	83 (65)	82 (64)	82 (65)
Methotrexate, n (%)	68 (54)	72 (56)	71 (56)
Methotrexate dose, mg/week, mean (SD)	16.7 (5.4)	15.6 (4.1)	15.9 (4.5)
Oral corticosteroids for PsA, n (%)	18 (14)	16 (13)	20 (16)
Dose equivalent to prednisone, mg/day, mean (SD)	6.0 (1.9)	6.4 (2.2)	6.4 (2.4)
NSAIDs for PsA, n (%)	71 (56)	69 (54)	77 (61)

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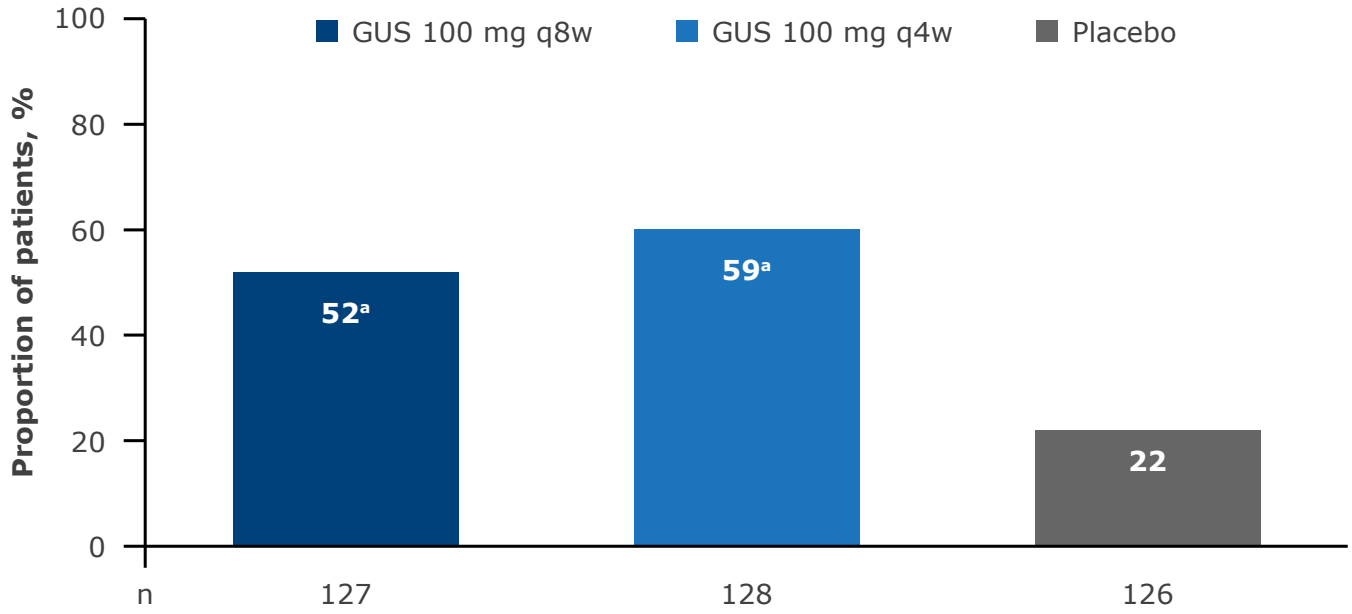
- A significantly greater proportion of patients achieved an ACR20 response at week 24 in the GUS groups vs the placebo group.[1,4]

ACR20 Response at Week 24[1,4]



[a]*P*<0.0001 vs placebo.

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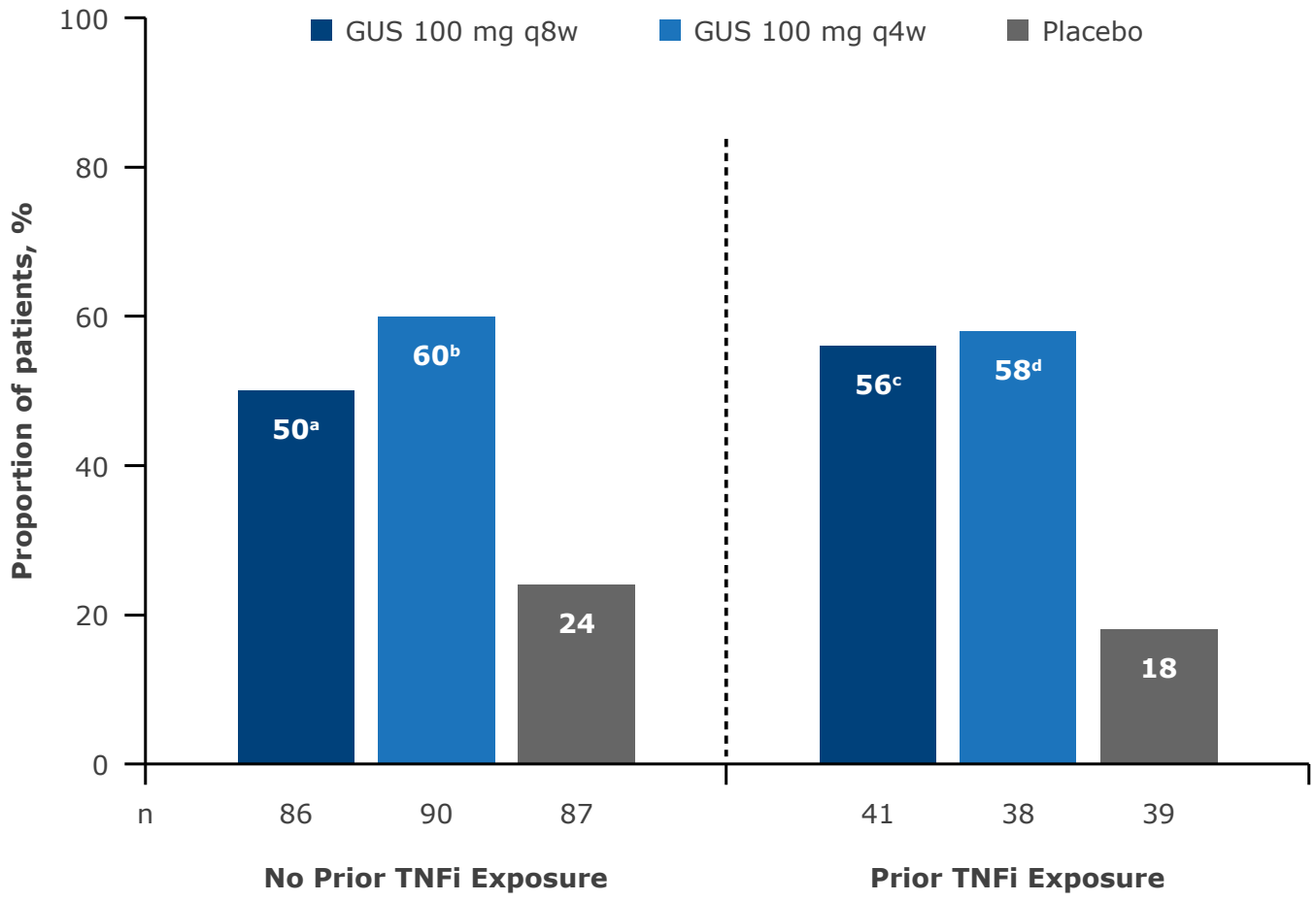
- A significantly greater proportion of patients with or without prior TNFi exposure achieved an ACR20 response at week 24 in the GUS groups vs the placebo group.[1,2]

ACR20 Response by Prior TNFi Exposure[1,2]



[a]*P*=0.0005 vs placebo; [b]*P*<0.0001 vs placebo; [c]*P*=0.0004 vs placebo; [d]*P*=0.0003 vs placebo.

- The proportion of patients who received methotrexate at baseline and achieved an ACR20 response at week 24 was 52% and 62% in the GUS q8w and q4w groups, respectively.[1,2]

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- Summary of results through week 24 are summarized in the following table:

Summary of Major Secondary Endpoint Results Through Week 24[1,4]

Endpoints	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
ACR20 response at week 16,[a] n (%)	66 (52)	77 (60)	32 (25)
P-value	<0.0001	<0.0001	-
ACR50 response at week 16,[a] n (%)	29 (23)	34 (27)	16 (13)
P-value	0.036	0.0057	-
ACR50 response at week 24,[a] n (%)	38 (30)	46 (36)	11 (9)
P-value	<0.0001	<0.0001	-
ACR70 response at week 24,[a] n (%)	15 (12)	26 (20)	7 (6)
P-value	0.069	0.0005	-
Change in HAQ-DI score from baseline at week 24, LS mean	-0.32	-0.40	-0.07
Adjusted *P*-value	<0.0001	<0.0001	-
IGA PsO score 0 or 1 and ≥2 grades of reduction from baseline at week 24,[b,c] n/N (%)	47/82 (57)	67/89 (75)	12/78 (15)
Adjusted *P*-value	<0.0001	<0.0001	-
Change in SF-36 PCS score from baseline at week 24, LS mean	6.10	6.87	1.96
Adjusted *P*-value	<0.0001	<0.0001	-

[a]Not part of the sequential testing procedure but was prespecified to be tested upon achieving statistical significance for ACR20 at week 24.
[b]IGA PsO score 0=cleared; 1=minimal.
[c]Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. Placebo, n=78; GUS 100 mg q8w, n=82; and GUS 100 mg q4w, n=89.

Summary of Uncontrolled Secondary Endpoint Results Through Week 24

Summary of Uncontrolled Secondary Endpoint Results Through Week 24[1,4]

Endpoints	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
HAQ-DI score ≥0.35 improvement from baseline at week 24,[a,b] n/N (%)	57/112 (51)	63/110 (57)	32/110 (29)
Unadjusted *P*-value[c]	0.0010	<0.0001	-
PASI75 at week 24,[d] n/N (%)	62/82 (76)	77/89 (86)	11/78 (14)
Unadjusted *P*-value[c]	<0.0001	<0.0001	-
PASI90 at week 24,[d] n/N (%)	41/82 (50)	56/89 (63)	9/78 (12)
Unadjusted *P*-value[c]	<0.0001	<0.0001	-
PASI100 at week 24,[d] n/N (%)	21/82 (26)	40/89 (45)	5/78 (6)
Unadjusted *P*-value[c]	0.0005	<0.0001	-
Change in SF-36 MCS score from baseline at week 24, LS mean	3.20	3.60	2.37
Unadjusted *P*-value[c]	0.40	0.21	-
MDA at week 24, n (%)	29 (23)	39 (30)	14 (11)
Unadjusted *P*-value[c]	0.012	0.0002	-
Change in DAS28-CRP score from baseline at week 24, LS mean	-1.43	-1.61	-0.70
Unadjusted *P*-value[c]	<0.0001	<0.0001	-

[a]Placebo, n=110; GUS 100 mg q8w, n=112; and GUS 100 mg q4w, n=110.
[b]Assessed in patients with HAQ-DI score 0.35 or greater at baseline.
[c]Unadjusted (nominal) P-values are not controlled for multiplicity and should be interpreted only as supportive.
[d]Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. Placebo, n=78; GUS 100 mg q8w, n=82; and GUS 100 mg q4w, n=89.

BSA, body surface area; DAS28-CRP, 28-joint disease activity score based on C-reactive protein; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire-Disability Index; LS, least squares; MCS, mental component summary; MDA, minimal disease activity; PASI75/90/100, ≥75/90/100% improvement in Psoriasis Area and Severity Index; SF-36, Short Form 36.

Summary of Uncontrolled Secondary Endpoint Results Through Week 24[1,4]

- Summary of results at week 52 are summarized in the following table:

Summary of Efficacy Results at Week 52[3]

Endpoints	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo to GUS 100 mg q4w n=126[a]
ACR20 response, %	59.8	73.4	56.3
Biologic-naïve[b]	60.5	75.6	58.6
TNFi-experienced[c]	58.5	68.4	51.3
ACR50 response, %	38.6	53.9	30.2
Biologic-naive[b]	38.4	56.7	33.3
TNFi-experienced[c]	39.0	47.4	23.1
ACR70 response, %	26.0	28.9	15.9
Biologic-naive[b]	27.9	33.3	18.4
TNFi-experienced[c]	22.0	18.4	10.3
IGA PsO score 0 or 1 and ≥2 grades of reduction from baseline,[d] %			
Biologic-naive[e]	66	85.2	71.2
TNFi-experienced[f]	58.6	75	61.5
Change from baseline in HAQ-DI score, LS mean[a,g]	-0.39	-0.51	-0.28
MDA[a]	29.9	39.1	25.4
Change from baseline in SF-36 PCS score, LS mean[a,g]	6.60	8.64	5.52
Change from baseline in SF-36 MCS score, LS mean[a,g]	4.42	4.28	4.07

[a]At 24 weeks, 114 of the 126 patients in the placebo group crossed over to the GUS 100 mg q4w group; 12 received placebo only before study drug discontinuation.
[b]Biologic-naive patients: placebo to GUS q4w, n=87 (82 patients crossed over at week 24, and 5 received placebo only before study drug discontinuation); GUS q8w, n=86; and GUS q4w, n=90.
[c]TNFi-experienced patients: placebo to GUS q4w, n=39 (32 patients crossed over at week 24, and 7 received placebo only before study drug discontinuation); GUS q8w, n=41; and GUS q4w, n=38.
[d]Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline.
[e]Biologic-naive patients: placebo to GUS 100 mg q4w, n=52 (47 patients crossed over at week 24 and 5 received placebo only before study drug discontinuation); GUS 100 mg q8w, n=53; and GUS q4w, n=61.
[f]TNFi-experienced patients: placebo to GUS 100 mg q4w, n=26 (21 patients crossed over at week 24, and 5 received placebo only before study drug discontinuation); GUS 100 mg q8w, n=29, and GUS q4w, n=28.
[g]LS mean adjusted for baseline DMARD use (yes/no), prior TNFi use (yes/no), and baseline value.

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- Summary of safety results through week 24 are summarized in the following table:

Summary of Safety Results Through Week 24[1]

	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
Duration of follow-up, weeks, mean	23.9	23.9	23.7
Patients with ≥1 AE, n (%)	68 (54)	71 (55)	75 (6)
AEs occurring in ≥5% of patients in any group, n (%)			
Increased ALT	8 (6)	5 (4)	3 (2)
Increased AST	9 (7)	3 (2)	3 (2)
Nasopharyngitis	16 (13)	7 (5)	8 (6)
Upper respiratory tract infection	7 (6)	11 (9)	8 (6)
Patients with ≥1 serious AE, n (%)	4 (3)[a]	0	5 (4)[b]
AEs leading to discontinuation of study treatment, n (%)	3 (2)[c]	1 (1)[d]	3 (2)[e]
Infection,[f] n (%)	33 (26)	31 (24)[g]	32 (25)
Serious infection	0	0	2 (2)[h]
Injection-site reaction, n (%)	2 (2)	1 (1)	0
Malignancy, n (%)	1 (1)[i]	0	0
Suicidal ideation, n (%)	1 (1)	0	1 (1)
Death, n (%)	0	0	1 (1)[j]

[a]One patient each with cervical dysplasia, ileus, plasma cell myeloma, and supraventricular arrhythmia.
[b]One patient each with cardiac failure, chronic obstructive pulmonary disease, limb abscess, pain, and upper respiratory tract infection.
[c]One patient each with bronchitis, plasma cell myeloma, and worsened psoriatic arthropathy.
[d]One patient with dyspepsia, gastritis, and hiatus hernia.
[e]One patient with cardiac failure and 2 patients with worsened PsO.
[f]AEs identified by investigators as infections.
[g]Includes 1 patient with fungal skin infection (mycotic infection) under the right breast reported at week 16.
[h]Two patients had serious infections (limb abscess and upper respiratory tract infection).
[i]One patient with plasma cell myeloma.
[j]Death due to cardiac failure.

Hematological Abnormalities Through Week 24

Hematological Abnormalities Through Week 24[1]

Hematological AE	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo n=126
Grade 2 neutropenia,[a] n	1	2	0
Grade 2 lymphopenia, n (%)	5 (2)		3 (2)
Grade 3 lymphopenia,[b] n	3[c]	0	0

[a]Transient and reversible abnormalities, resolved spontaneously without treatment, were not associated with infections, and did not result in discontinuation.
[b]All occurrences of grade 3 abnormalities were considered transient with return to pretreatment levels by the next visit.
[c]Of these, 2 patients had experienced grade 2 abnormalities before the first dose of GUS.

AE, adverse event; GUS, guselkumab; q4w, every 4 weeks; q8w, every 8 weeks.

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- Summary of safety results through week 60 (365 patient-years of follow-up) are summarized in the following table:

Summary of Safety Results Through Week 60[3]

	GUS 100 mg q8w n=127	GUS 100 mg q4w n=128	Placebo to GUS 100 mg q4w (Weeks 24-60)[a] n=114
Duration of follow-up, years, mean	1.1	1.1	0.7
Overall exposure/follow-up, patient-years	142	146	77
All AEs, n (%)	87 (68.5)	89 (69.5)	55 (48.2)
Serious AEs, n (%)	8 (6.3)	4 (3.1)	4 (3.5)
AEs leading to discontinuation of study treatment, n (%)	5 (3.9)	1 (0.8)	3 (2.6)
Infection, n (%)	54 (42.5)	49 (38.3)	30 (26.3)
Serious infection, n (%)	2 (1.6)[b]	0	2 (1.8)[c]

[a]At 24 weeks, patients in the placebo group crossed over to the GUS 100 mg q4w group; only results from weeks 24-52 are summarized for this group.
[b]One patient each with bronchitis and cellulitis during weeks 24-52.
[c]One patient each with pyelonephritis and urosepsis during weeks 24-52.

- Time-adjusted incidences (per 100 patient-years of follow-up) for patients with AEs, SAEs, AEs leading to treatment discontinuation, and serious infections were similar across treatment groups.[3]
- Death or inflammatory bowel disease were not reported in patients treated with GUS.[3]
- None of the patients had opportunistic infection, active tuberculosis, anaphylactic reaction, or serum sickness-like reaction.[3]

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AE	Adverse event	**MDA**	Minimal Disease Activity
ACR	American College of Rheumatology	**NRI**	Nonresponder imputation
ACR20/ 50/70	≥20/50/70% improvement in the ACR response criteria	**NSAIDs**	Nonsteroidal anti-inflammatory drugs
ALT	Alanine aminotransferase	**PASI**	Psoriasis Area and Severity Index
AST	Aspartate aminotransferase	**PASI75/ 90/100**	≥75/90/100% improvement in PASI
BSA	Body surface area	**PCS**	Physical Component Summary
CASPAR	Classification Criteria or Psoriatic Arthritis	**PsA**	Psoriatic arthritis
CRP	C-reactive protein	**PsO**	Psoriasis
DAS28	28-Joint Disease Activity Score	**q4w**	Every 4 weeks
DMARDs	Disease-modifying antirheumatic drugs	**q8w**	Every 8 weeks
EE	Early escape	**R**	Randomized
GUS	Guselkumab	**SAE**	Serious adverse event
HAQ-DI	Health Assessment Questionnaire-Disability Index	**SC**	Subcutaneously
IGA	Investigator's Global Assessment	**SD**	Standard deviation
IQR	Interquartile range	**SF-36**	Short Form-36
LEI	Leeds Enthesitis Index	**TNFi**	Tumor necrosis factor inhibitor(s)
LS	Least squares	**US**	United States
MCS	Mental Component Summary	**VAS**	Visual Analog Scale

A literature search of Ovid MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File databases (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 10 July 2020.

Summarized in this response are data from the phase 3 clinical trial, DISCOVER-1, that evaluated the efficacy and safety of GUS for the treatment of adult patients with active PsA through week 52. Additional data regarding the use of GUS for the treatment of adult patients with active PsA are available upon request.

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1. Deodhar A, Helliwell PS, Boehncke WH, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNFα inhibitor treatment (DISCOVER-1):a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1115-1125.
2. Deodhar A, Helliwell PS, Boehncke WH, et al. Supplement to: Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNFα inhibitor treatment (DISCOVER-1):a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1115-1125.
3. Ritchlin C, Helliwell P, Boehncke WH, et al. Guselkumab, an IL-23 inhibitor that specifically binds to the IL23p19-subunit, for active psoriatic arthritis: one year results of a phase 3, randomized, double-blind, placebo-controlled study of patients who were biologic-naive or TNFα inhibitor-experienced. Poster presented at: The European League Against Rheumatism (EULAR); June 3-6, 2020; E-congress.
4. Data on File. Statistical Analysis Plan CNTO1959PSA3001. Janssen Research & Development, LLC. EDMS-ERI-146207736. US-SRSM-3683; 2019.