TREMFYA® (guselkumab)
Treatment of active psoriatic arthritis (DISCOVER-1)

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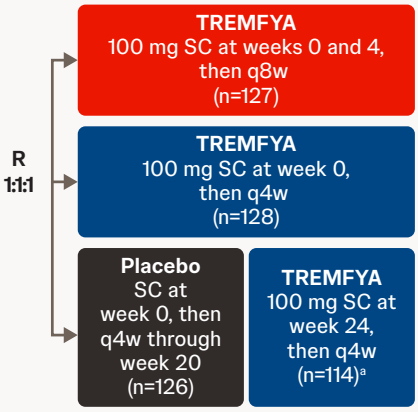
Overview[1-3]

A phase 3, randomized, multicenter, double-blind, placebo-controlled study was conducted to evaluate the efficacy and safety of TREMFYA 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]

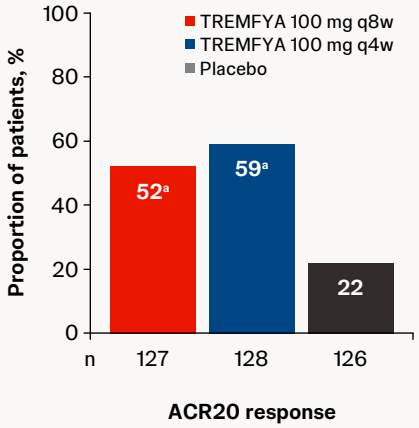


Safety follow-up: up to 60 weeks

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

Primary endpoint[1,4]

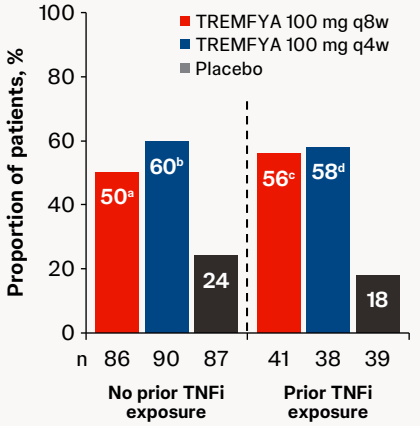
A significantly greater proportion of patients achieved an ACR20 response at week 24 in the TREMFYA groups vs the placebo group



[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 TREMFYA 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	TREMFYA 100 mg q8w (n=127)	TREMFYA 100 mg q4w (n=128)	Placebo (n=126)
Mean duration of follow-up, weeks	23.9	23.9	23.7
≥1 AE[a]	68 (54)	71 (55)	75 (60)
≥1 SAE[a]	4 (3)	0	5 (4)
Treatment discontinuation due to AEs[a]	3 (2)	1 (1)	3 (2)
Through week 60	**TREMFYA 100 mg q8w (n=127)**	**TREMFYA 100 mg q4w (n=128)**	**Placebo to TREMFYA 100 mg q4w (n=114)**
Mean duration of follow-up, weeks	58.3	59.5	35.3
All AEs[a]	87 (68.5)	89 (69.5)	55 (48.2)
SAEs[a]	8 (6.3)	4 (3.1)	4 (3.5)
Treatment discontinuation due to AEs[a]	5 (3.9)	1 (0.8)	3 (2.6)

[a]Data are n (%) unless otherwise noted.

Note: ACR, American College of Rheumatology; ACR20, ≥20% improvement in the ACR response criteria; AE, adverse event; CASPAR, Classification Criteria for Psoriatic Arthritis; CRP, C-reactive protein; DMARDs, disease-modifying antirheumatic drugs; NSAIDs, nonsteroidal anti-inflammatory drugs; PsA, psoriatic arthritis; q4w, every 4 weeks; q8w, every 8 weeks; R, randomized; SAE, serious adverse event; SC, subcutaneously; TNFi, tumor necrosis factor inhibitor(s).

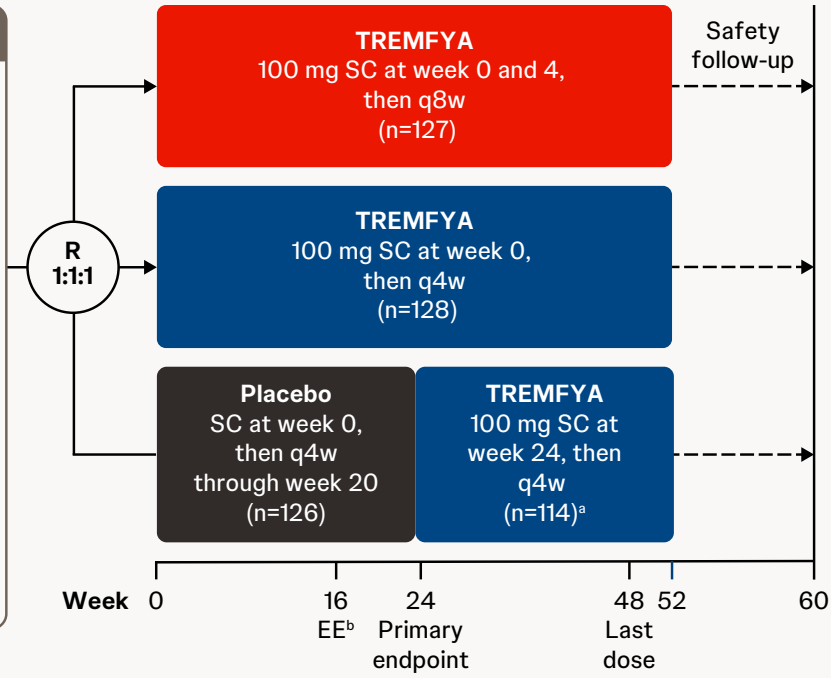
TREMFYA® (guselkumab)
Treatment of active psoriatic arthritis (DISCOVER-1)

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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 TREMFYA 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 PASI 75, PASI 90, and PASI 100 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.

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

Summary of select patient baseline demographics[1]

Characteristic	TREMFYA 100 mg q8w n=127	TREMFYA 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]

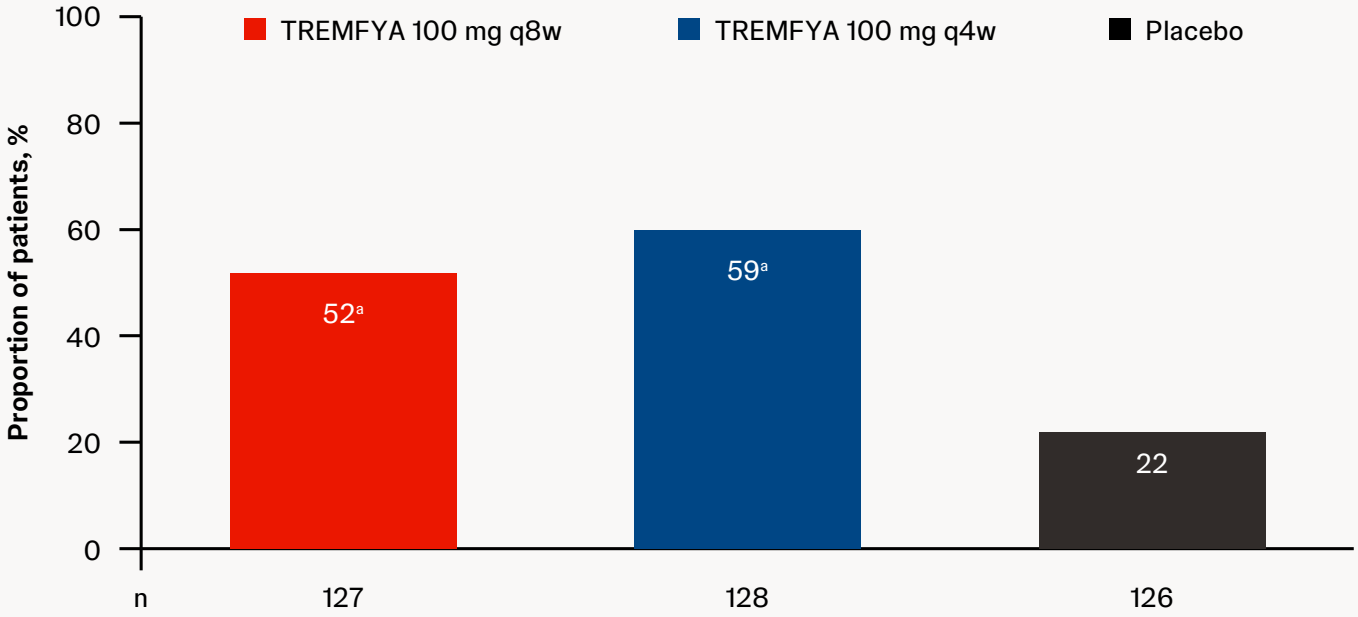
Characteristic	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo n=126
Previous TNFi use, n (%)	41 (32)	38 (30)	39 (31)
One previous TNFi	34 (27)	33 (26)	35 (28)
Two previous TNFi	7 (6)	5 (4)	4 (3)
Patients who did not respond to previous TNFi	15 (12)	17 (13)	12 (10)
Previous apremilast use, 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 TREMFYA groups vs the placebo group.[1,4]

ACR20 response at week 24[1,4]



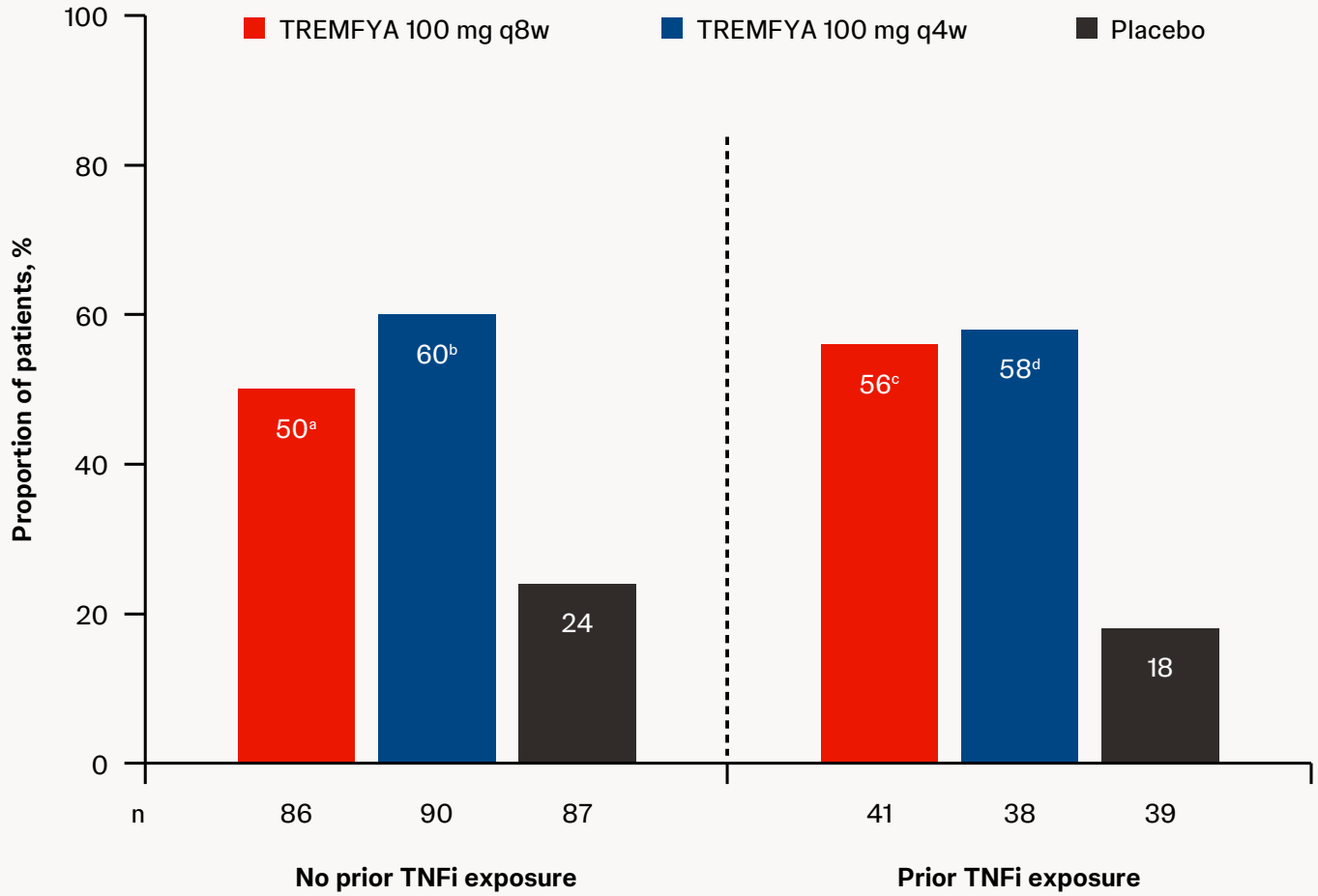
[a]*P*<0.0001 vs placebo.

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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 TREMFYA 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 TREMFYA 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	TREMFYA 100 mg q8w n=127	TREMFYA 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;TREMFYA 100 mg q8w, n=82; and TREMFYA 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	TREMFYA 100 mg q8w n=127	TREMFYA 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; TREMFYA 100 mg q8w, n=112; and TREMFYA 100 mg q4w, n=110.
[b]Assessed in patients with HAQ-DI score ≥0.35 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; TREMFYA 100 mg q8w, n=82; and TREMFYA 100 mg q4w, n=89.

BSA, body surface area; DAS28-CRP, 28-joint disease activity score based on C-reactive protein; 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; q4w, every 4 weeks; q8w, every 8 weeks; SF-36, Short Form 36.

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- Summary of results at week 52 are summarized in the following table.[1]

Summary of efficacy results at week 52[3]

Endpoints	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo to TREMFYA 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-naïve[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-naïve[b]	27.9	33.3	18.4
TNFi-experienced[c]	22.0	18.4	10.3
IGA PsO score 0/1[d] and ≥2 grades of reduction from baseline,[e,f] %	63.4	82.0	67.9
Biologic-naïve[b]	66.0	85.2	71.2
TNFi-experienced[c]	58.6	75.0	61.5
Change from baseline in HAQ-DI score, LS mean[a,i]	-0.4	-0.5	-0.3
MDA,[a] %	29.9	39.1	25.4
Change from baseline in SF-36 PCS score, LS mean[a,i]	6.6	8.6	5.5
Change from baseline in SF-36 MCS score, LS mean[a,i]	4.4	4.3	4.1

[a]At 24 weeks, 114 of the 126 patients in the placebo group crossed over to the TREMFYA 100 mg q4w group; 12 patients received placebo only before study drug discontinuation. [b]Biologic-naive patients: placebo to TREMFYA q4w, n=87(82 patients crossed over at week 24, and 5 patients received placebo only before study drug discontinuation); TREMFYA q8w, n=86; and TREMFYA q4w, n=90. [c]TNFi-experienced patients: placebo to TREMFYA q4w, n=39 (32 patients crossed over at week 24, and 7 patients received placebo only before study drug discontinuation); TREMFYA q8w, n=41; and TREMFYA q4w, n=38. [d]IGA PsO score 0=clear; 1=almost clear. [e]Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. [f]Placebo to TREMFYA q4w, n=78 (68 patients crossed over at week 24 and 10 patients received placebo only before study discontinuation); TREMFYA 100 mg q8w, n=82; and TREMFYA q4w, n=89. [g]Biologic-naive patients: placebo to TREMFYA 100 mg q4w, n=52 (47 patients crossed over at week 24 and 5 patients received placebo only before study drug discontinuation); TREMFYA 100 mg q8w, n=53; and TREMFYA q4w, n=61. [h]TNFi-experienced patients: placebo to TREMFYA 100 mg q4w, n=26 (21 patients crossed over at week 24, and 5 patients received placebo only before study drug discontinuation); TREMFYA 100 mg q8w, n=29; and TREMFYA q4w, n=28. [i]LS mean adjusted for baseline DMARD use (yes/no), prior TNFi use (yes/no), and baseline value.

Summary of additional efficacy results at week 52

Summary of additional efficacy results at week 52[3]

Endpoints	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo to TREMFYA 100 mg q4w n=126
HAQ-DI score ≥0.35 improvement from baseline through week 52,[a,b] %	51.8	67.3	45.5
PASI 75,[c,d] %	73.2	93.3	71.8
PASI 90,[c,d] %	61.0	75.3	61.5
Biologic-naïve[e]	66.0	75.4	65.4
TNFi-experienced[f]	51.7	75.0	53.8
PASI 100,[c,d] %	43.9	64.0	52.6
Biologic-naïve[e]	50.9	67.2	59.6
TNFi-experienced[f]	31.0	57.1	38.5

[a]Placebo to TREMFYA q4w, n=110 (100 patients crossed over at week 24, and 10 patients received only placebo before study drug discontinuation); TREMFYA q8w, n=112; and TREMFYA q4w, n=110.
[b]Assessed in patients with HAQ-DI score of ≥0.35 at baseline.
[c]Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline.
[d]Placebo to TREMFYA q4w, n=78 (68 patients crossed over at week 24, and 10 patients received placebo only before study drug discontinuation); TREMFYA q8w, n=82; and TREMFYA q4w, n=89.
[e]Biologic-naïve patients: placebo to TREMFYA q4w, n=52 (47 patients crossed over at week 24 and 5 patients received placebo only before study drug discontinuation); TREMFYA q8w, n=53; and TREMFYA q4w, n=61.
[f]TNFi-experienced patients: placebo to TREMFYA q4w, n=26 (21 patients crossed over at week 24, and 5 patients received placebo only before study drug discontinuation); TREMFYA q8w, n=29; and TREMFYA q4w, n=28.

BSA, body surface area; HAQ-DI, Health Assessment Questionnaire-Disability Index; IGA, Investigator's Global Assessment; PASI 75/90/100, ≥75/90/100% improvement in Psoriasis Area and Severity Index; q4w, every 4 weeks; q8w, every 8 weeks; TNFi, tumor necrosis factor inhibitor.

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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]

	TREMFYA 100 mg q8w n=127	TREMFYA 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 (60)
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	TREMFYA 100 mg q8w n=127	TREMFYA 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 TREMFYA.

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

TREMFYA® (guselkumab)
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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]

	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo to TREMFYA 100 mg q4w (Weeks 24-60)[a] n=114
Duration of follow-up, weeks, mean	58.3	59.5	35.3
Overall exposure/follow-up, patient-years	142	146	77
All AEs, n (%)	87 (68.5)	89 (69.5)	55 (48.2)
Total patient-years	71	69	53
Incidence/100 patient-years	121.9	129.0	104.3
Serious AEs, n (%)	8 (6.3)	4 (3.1)	4 (3.5)
Total patient-years	136	144	75
Incidence/100 patient-years	5.9	2.8	5.3
AEs leading to discontinuation of study treatment, n (%)	5 (3.9)	1 (0.8)	3 (2.6)
Total patient-years	141	146	76
Incidence/100 patient-years	3.6	0.7	3.9
Infection, n (%)	54 (42.5)	49 (38.3)	30 (26.3)
Total patient-years	104	110	66
Incidence/100 patient-years	51.7	44.6	45.4
Serious infection, n (%)	2 (1.6)[b]	0	2 (1.8)[c]
Total patient-years	141	146	76
Incidence/100 patient-years	1.4	0	2.6

[a]At 24 weeks, patients in the placebo group crossed over to the TREMFYA 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 24-60.
[c]One patient each with pyelonephritis and urosepsis during weeks 24-60.

- 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, MACE, or inflammatory bowel disease were not reported in patients treated with TREMFYA.[3]
- None of the patients had uveitis, opportunistic infection, active tuberculosis, anaphylactic reaction, serum sickness, or serum sickness-like reaction.[3]

Decrease in neutrophil, platelet, and WBC count through week 60

Increase in AST, ALT, and blood bilirubin through week 60

Decrease in neutrophil, platelet, and WBC counts through week 60[5]

AEs by maximum NCI-CTCAE grade	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo to TREMFYA 100 mg q4w n=126
Decreased neutrophil count, n (%)			
Grade 1 (<LLN to 1.5x10^9/L)	9 (7.1)	13 (10.2)	4 (3.5)
Grade 2 (<1.5 to 1.0×10^9/L)	1 (0.8)	3 (2.3)	0
Grade 3 (<1.0 to 0.5×10^9/L)	0	0	1 (0.9)[b]
Grade 4 (<0.5×10^9/L)	0	0	0
Decreased platelet count, n (%)			
Grade 1 (<LLN to 75.0×10^9/L)	8 (6.3)	3 (2.3)	3 (2.7)
Grade 2 (<75.0 to 50.0×10^9/L)	1 (0.8)[c]	0	0
Grade 3 or 4 (<50.0×10^9/L)	0	0	0
Decreased WBC count, n (%)			
Grade 1 (<LLN to 3.0×10^9/L)	7 (5.6)	14 (10.9)	5 (4.4)
Grade 2 (<3.0 to 2.0×10^9/L)[d]	1 (0.8)	3 (2.3)	1 (0.9)
Grade 3 or 4 (<2.0×10^9/L)	0	0	0

[a]Patients received placebo during weeks 0-24; only results from weeks 24-52 are summarized for this group.
[b]Resolved in 8 days without treatment; not associated with an infection.
[c]Resolved spontaneously at the subsequent visit without treatment; not associated with a bleeding event.
[d]Associated with infection (pulpitis dental, tooth abscess) before week 24 and interruption of TREMFYA for 1 patient; neither associated with infection nor led to study drug discontinuation for other patients.

AE, adverse event; LLN, lower limit of normal; NCI-CTCAE, National Cancer Institute - Common Terminology Criteria for Adverse Events; q4w, every 4 weeks; q8w, every 8 weeks; WBC, white blood cell.

Increase in AST, ALT, and blood bilirubin through week 60[5]

AEs by maximum NCI-CTCAE grade	TREMFYA 100 mg q8w n=127	TREMFYA 100 mg q4w n=128	Placebo to TREMFYA 100 mg q4w n=126
Increased ALT, n (%)			
Grade 1 (>1 to 3×ULN)	43 (34.1)	67 (52.3)	32 (28.3)
Grade 2 (>3 to 5×ULN)	4 (3.2)	3 (2.3)	4 (3.5)
Grade 3 (>5 to 20×ULN)	1 (0.8)[b]	0	0
Grade 4 (>20xULN)	0	0	0
Increased AST, n (%)			
Grade 1 (>1 to 3×ULN)	35 (27.8)	42 (32.8)	25 (22.1)
Grade 2 (>3 to 5×ULN)	4 (3.2)	3 (2.3)	3 (2.7)
Grade 3 (>5 to 20×ULN)[c]	1 (0.8)	1 (0.8)	1 (0.9)
Grade 4 (>20×ULN)	0	0	0
Increased blood bilirubin, n (%)			
Grade 1 (>ULN to 1.5×ULN)	1 (0.8)	12 (9.4)	8 (7.1)
Grade 2 (>1.5 to 3×ULN)	5 (4.0)[d]	0	2 (1.8)
Grade 3 or 4 (>3×ULN)	0	0	0

[a]Patients received placebo during weeks 0-24; only results from weeks 24-52 are summarized for this group.
[b]In a patient with grade 1 ALT and grade 2 AST elevations at initial screening and concomitant medications including methotrexate, celecoxib, isoniazid, and epinastine; accompanied by grade 2 AST increase and AE of ultrasound-confirmed fatty liver at week 36; ALT and AST decreased to grade 1 after 14 days without interrupting study drug; followed by grade 2 total bilirubin increase (>2×ULN) at week 52.
[c]All resolved over time; none led to study drug discontinuation.
[d]Bilirubin >2×ULN was observed in 2 patients including an elderly individual with elevated bilirubin at baseline and throughout the study, with a medical history of Gilbert's syndrome; no ALT/AST increase of grade ≥2; no intervention required. Details of the second patient are described in footnote b.

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; NCI-CTCAE, National Cancer Institute - Common Terminology Criteria for Adverse Events; q4w, every 4 weeks; q8w, every 8 weeks; ULN, upper limit of normal.

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AE	Adverse event	**NRI**	Nonresponder imputation
ACR	American College of Rheumatology	**NCI-CTCAE**	National Cancer Institute - Common Terminology Criteria for Adverse Events
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	**PASI 75/ 90/100**	≥75/90/100% improvement in PASI
BSA	Body surface area	**PCS**	Physical Component Summary
CASPAR	Classification Criteria For 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
HAQ-DI	Health Assessment Questionnaire-Disability Index	**SAE**	Serious adverse event
IGA	Investigator's Global Assessment	**SC**	Subcutaneously
IQR	Interquartile range	**SD**	Standard deviation
LEI	Leeds Enthesitis Index	**SF-36**	Short Form-36
LLN	Lower limit of normal	**TNFi**	Tumor necrosis factor inhibitor(s)
LS	Least squares	**ULN**	Upper limit of normal
MACE	Major adverse cardiovascular events	**US**	United States
MCS	Mental Component Summary	**VAS**	Visual Analog Scale
MDA	Minimal Disease Activity	**WBC**	White blood cell

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A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) was conducted on 20 January 2026.

Summarized in this response are data from the phase 3 clinical trial, DISCOVER-1, that evaluated the efficacy and safety of TREMFYA for the treatment of adult patients with active PsA through week 60.

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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 CT, Helliwell PS, Boehncke WH, et al. Guselkumab, an inhibitor of the IL-23p19 subunit, provides sustained improvement in signs and symptoms of active psoriatic arthritis: 1 year results of a phase III randomised study of patients who were biologic-naïve or TNFα inhibitor-experienced. *RMD Open*. 2021;7(1):e001457.
4. Data on File. Statistical Analysis Plan CNTO1959PSA3001. Janssen Research & Development, LLC. EDMS-ERI-146207736; 2019.
5. Ritchlin CT, Helliwell PS, Boehncke WH, et al. Supplement to: Guselkumab, an inhibitor of the IL-23p19 subunit, provides sustained improvement in signs and symptoms of active psoriatic arthritis: 1 year results of a phase III randomised study of patients who were biologic-naïve or TNFα inhibitor-experienced. *RMD Open*. 2021;7(1):e001457.

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