TREMFYA® (guselkumab)
Overview of VOYAGE 2 clinical trial

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Overview[1]

Phase 3, multicenter, randomized, double-blind PBO- and active comparator-controlled study (N=992) that evaluated the efficacy and safety of TREMFYA compared with PBO and ADA in patients with moderate to severe plaque PsO



Select eligibility criteria[1-3]

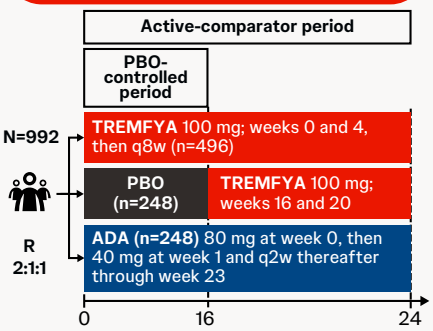
Select inclusion criteria[1]

- Adults with plaque PsO ≥6 months who were candidates for phototherapy or systemic therapy were eligible for enrollment
- Baseline IGA score ≥3
- PASI score ≥12
- ≥10% BSA involvement

Select exclusion criteria[2,3]

- Patients with guttate, erythrodermic, pustular, or drug-induced PsO
- Patients with a history or symptoms of active tuberculosis

Study design[1,4,a]

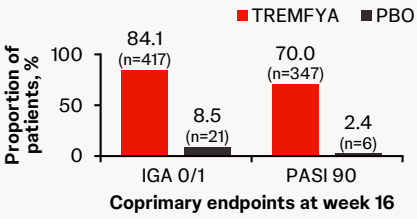


Week 28-76 consisted of a randomized withdrawal and re-treatment period.

OLE through 5 years:[h,i] After week 76, patients initially randomized to TREMFYA or PBO continued TREMFYA q8w through the OLE; patients initially randomized to ADA started TREMFYA q8w in the retreatment period on or after week 28 and then continued through the OLE

Coprimary and other efficacy endpoints[1,4]

At week 16, an IGA 0/1 and PASI 90 rates were achieved by significantly more TREMFYA vs PBO patients (*P*<0.001)



Coprimary endpoints at week 16

At week 252 (OLE):

- In the combined TREMFYA group, IGA 0/1 and PASI 90 scores analyzed using TFR were observed in 85.0% (n=559) and 82.0% (n=560) of patients, respectively

Select secondary efficacy endpoints[1]

	TREMFYA 100 mg (n=496)	ADA 40 mg (n=248)
Week 16		
IGA 0/1	84.1%	67.7%
PASI 75	86.3%	68.5%
PASI 90	70.0%	46.8%
Week 24		
IGA 0	51.8%	31.5%
IGA 0/1	83.5%	64.9%
PASI 90	75.2%	54.8%
Weeks 28-48		
Median time to loss of PASI 90 response	15.2 weeks (23 weeks after the last TREMFYA dose)	

Safety[1,4]

Through week 16:

- The proportion of patients with ≥1 AE was comparable across the treatment groups (PBO, 44.8%; TREMFYA, 47.6%; ADA, 48.4%)
- SAEs (≥1) were reported in 1.2%, 1.6%, and 2.4% in the PBO, TREMFYA, and ADA groups, respectively

Through week 264 (OLE):

- The proportion of patients with ≥1 AE in the all TREMFYA (N=727), combined TREMFYA (N=947), and ADA to TREMFYA (N=220) groups were 85.8%, 85.9%, and 85.9%, respectively
- SAEs (≥1) were reported in 16.2%, 16.1%, and 15.5% of patients in the all TREMFYA, combined TREMFYA, and ADA to TREMFYA groups, respectively

Note: Patients meeting treatment failure criteria before week 16 and patients not returning for week-16 evaluation were considered nonres for the week-16 primary end point. For patients randomized to PBO, only those crossing over to TREMFYA at or after week 16 were included in efficacy analyses after week 16.[1]

Abbreviations: ADA, adalimumab; AE, adverse event; BSA, body surface area; IGA 0/1, Investigator's Global Assessment cleared/minimal (IGA 0, cleared; IGA 1, minimal); nonres, nonresponders; OLE, open-label extension; PASI 75/90, ≥75%/90% improvement in the Psoriasis Area and Severity Index score from baseline; PBO, placebo; PsO, psoriasis; q2w, every 2 weeks; q8w, every 8 weeks; R, randomization; res, responders; SAE, severe adverse event; SE, secondary endpoint; TFR, treatment failure rules.

[a]To maintain blinding, both TREMFYA and ADA PBOs were administered, as necessary. [b]At week 28, TREMFYA-treated patients achieving ≥PASI 90 from baseline were randomized in a 1:1 ratio to TREMFYA or PBO. [c]Upon loss of ≥50% of week-28 PASI 90 response or if prerequisite loss of week-72 PASI 90 response was not observed, patients were initiated or retreated with TREMFYA. [d]Patients with <PASI 90. [e]Patients with ≥PASI 90 from baseline at week 28. [f]TREMFYA was started at week 28 (5 weeks after the last dose of ADA). [g]Proportions of patients achieving an IGA score of IGA 0/1 and PASI 90 at week 16 in the TREMFYA group. [h]The last dose of TREMFYA was administered at week 252; through 252 weeks for efficacy and 264 weeks for safety. [i]TFR-defined patients as treatment failures if discontinuation occurred due to lack of efficacy, worsening of PsO, or use of a protocol-prohibited PsO treatment.

TREMFYA® (guselkumab)
Overview of VOYAGE 2 clinical trial

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VOYAGE 2 is a phase 3, multicenter, randomized, double-blind, PBO- and active comparator-controlled study that evaluated the efficacy and safety of TREMFYA compared with PBO and ADA in patients with moderate to severe plaque PsO. The study was conducted at 115 global sites from November 2014 to May 2016.[1]

Select inclusion criteria[1]

- Patients (≥18 years of age) with a diagnosis of plaque PsO for ≥6 months before first study drug administration who were candidates for phototherapy or systemic therapy
- Baseline IGA score ≥3
- PASI score ≥12
- BSA involvement of ≥10%

Select exclusion criteria[2,3]

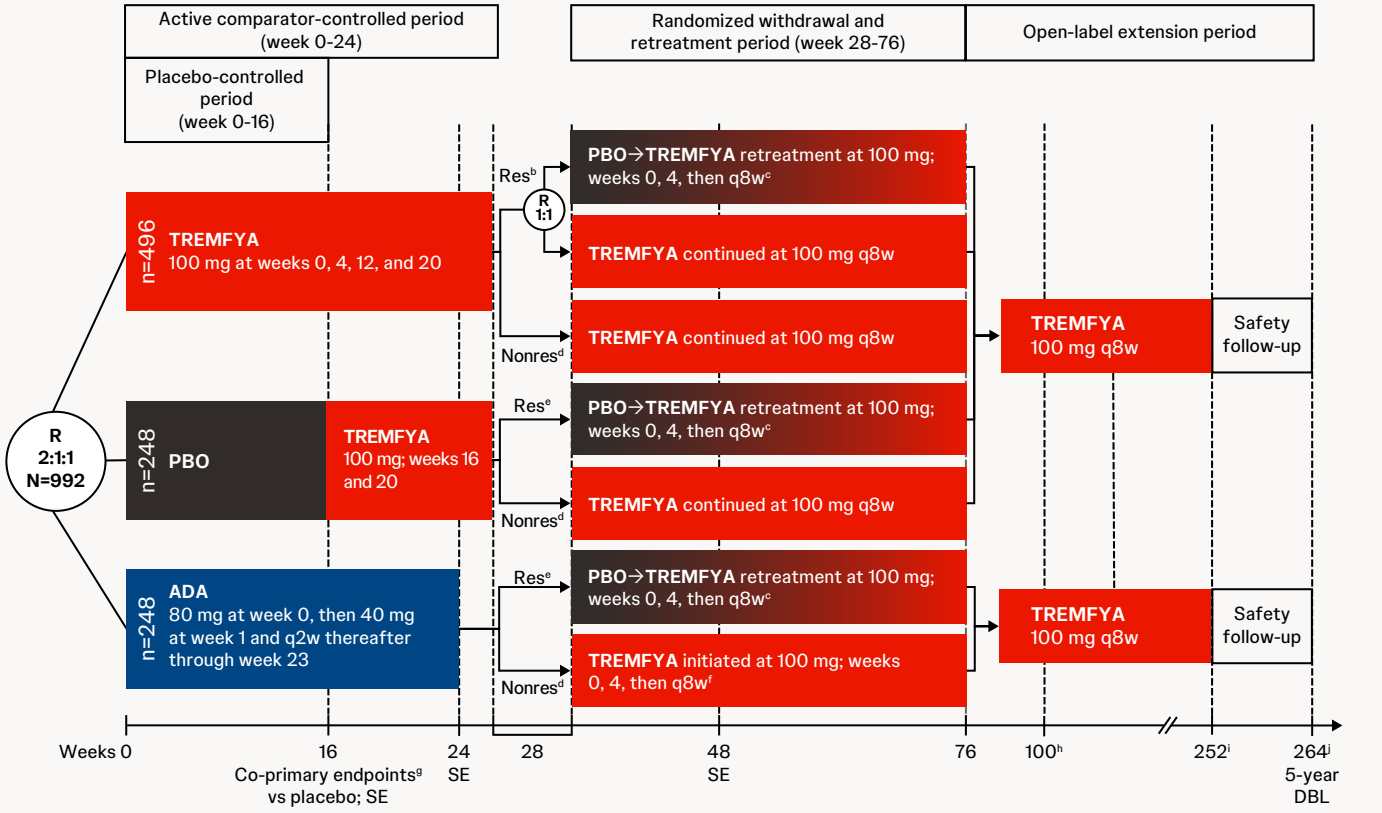
- Patients with guttate, erythrodermic, pustular, or drug-induced PsO
- Patients with a history or symptoms of active tuberculosis

Study design

Eligible patients (N=992) were randomized 2:1:1 to 1 of 3 treatment arms (TREMFYA [n=496], PBO [n=248], or ADA [n=248]). After week 76, patients initially randomized to TREMFYA or PBO continued TREMFYA q8w through the OLE; patients initially randomized to ADA started TREMFYA q8w in the retreatment period on or after week 28 and then continued through the OLE.[1,4]

Click to see VOYAGE 2 study design through 264 weeks

VOYAGE 2 study design through 264 weeks[1,4,a]



[a]To maintain blinding, both TREMFYA and ADA PBOs were administered, as necessary.
[b]At week 28, TREMFYA-treated patients achieving ≥PASI 90 from baseline were randomized in a 1:1 ratio to TREMFYA or PBO.
[c]Upon loss of ≥50% of week-28 PASI 90 response or if prerequisite loss of week-72 PASI 90 response was not observed, patients were initiated or retreated with TREMFYA.
[d]Patients with <PASI 90.
[e]Patients with ≥PASI 90 from baseline at week 28.
[f]TREMFYA was started at week 28 (5 weeks after the last dose of ADA).
[g]Proportions of patients achieving IGA 0/1 and PASI 90 at week 16 in the TREMFYA group.
[h]Due to inclusion of the randomized withdrawal and retreatment period (weeks 28-76), some patients initiated or were retreated with TREMFYA q8w beginning at week 76. Efficacy compared to baseline for TREMFYA-treated patient was evaluated starting at week 100 to allow time for adequate response.
[i]The last dose of TREMFYA was administered at week 252; efficacy was evaluated through week 252.
[j]Safety was evaluated through week 264.

ADA, adalimumab; DBL, data-base lock; nonres, nonresponders; PBO, placebo; PASI90; ≥90% improvement in Psoriasis Area and Severity Index score from baseline; q2w; every 2 weeks; q8w; every 8 weeks; res, responders; R, randomization; SE, secondary endpoint.

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Coprimary endpoints[1]

- Proportion of patients achieving an IGA score of cleared (0) or minimal (1) disease and the proportion of patients who achieved a PASI 90 response at week 16 in the TREMFYA group compared with the PBO group.

Major secondary endpoints[1,a]

	TREMFYA vs PBO	TREMFYA vs ADA	Maintenance vs withdrawal	Study visit
Proportion of patients who achieve IGA 0[b,5]	-	x	-	Week 24
Proportion of patients who achieve IGA 0/1[b,5]	-	x	-	Week 24
Proportion of patients who achieve PASI 90[b,5]	-	x	-	Week 24
Time to loss of PASI 90 response	-	-	x	Week 28-48
Change from baseline in the DLQI score	x	-	-	Week 16
Proportion of patients who achieve IGA 0/1[b,c]	-	x	-	Week 16
Proportion of patients who achieve PASI 90[b,c]	-	x	-	Week 16
Proportion of patients who achieve PASI 75[b,c]	-	x	-	Week 16
Proportion of patients who achieve ss-IGA 0/1[d]	x	-	-	Week 16
Change from baseline in the PSSD symptom score	x	-	-	Week 16
Proportion of patients who achieved PSSD symptom score 0[e]	-	x	-	Week 24

"x" indicates major secondary endpoint was measured against listed comparator at listed study visit and "-" indicates major secondary endpoint was not measured against listed comparator at listed study visit.
[a]To control the overall type 1 error rate, the primary analysis and major secondary analyses were tested using a fixed sequence method. Specifically, the first major secondary endpoint was tested only if the coprimary endpoints were positive, and subsequent endpoints were tested only if the preceding endpoint was positive.
[b]Tested for superiority of the TREMFYA group compared with the ADA group.
[c]Tested for noninferiority of the TREMFYA group compared with the ADA group.
[d]Included only randomized patients with baseline ss-IGA score ≥2 and who achieved ≥2-grade improvement.
[e]Included only randomized patients with PSSD symptom score ≥1 at baseline.

- Safety was monitored throughout the study.[1]

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- Demographic and disease characteristics were comparable across treatment groups at baseline.[1]

Demographic and disease characteristics[1]

	TREMFYA (N=496)	ADA (N=248)	PBO (N=248)	Total (N=992)
Age, years, mean (±SD)	43.7 (±12.2)	43.2 (±11.9)	43.3 (±12.4)	43.5 (±12.2)
Men, n (%)	349 (70.4)	170 (68.5)	173 (69.8)	692 (69.8)
Race, n (%)				
White	408 (82.3)	200 (80.6)	206 (83.1)	814 (82.1)
Asian	72 (14.5)	37 (14.9)	27 (10.9)	136 (13.7)
Black	6 (1.2)	5 (2.0)	8 (3.2)	19 (1.9)
BMI, kg/m^2, mean (±SD)	29.6 (±6.5)	29.6 (±6.6)	29.6 (±6.6)	29.6 (±6.5)
Duration of PsO, years, mean (±SD)	17.9 (±12.0)	17.6 (±11.7)	17.9 (±11.9)	17.8 (±11.9)
BSA involvement, %, mean (±SD)	28.5 (±16.4)	29.1 (±16.7)	28.0 (±16.5)	28.5 (±16.5)
IGA score 0-4, n (%)				
Mild, 2	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.1)
Moderate, 3	380 (76.6)	195 (78.6)	191 (77.0)	766 (77.2)
Severe, 4	115 (23.2)	53 (21.4)	57 (23.0)	225 (22.7)
PASI score 0-72, mean (±SD)	21.9 (±8.8)	21.7 (±9.0)	21.5 (±8.0)	21.8 (±8.6)
ss-IGA score 0-4, n (%)	423 (85.3)	205 (82.7)	212 (85.5)	840 (84.7)
Absence of disease, 0	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Very mild, 1	15 (3.5)	11 (5.4)	10 (4.7)	36 (4.3)
Mild, 2	80 (18.9)	43 (21.0)	33 (15.6)	156 (18.6)
Moderate, 3	267 (63.1)	118 (57.6)	133 (62.7)	518 (61.7)
Severe, 4	61 (14.4)	33 (16.1)	36 (17.0)	130 (15.5)
DLQI score 0-30, n	495	247	248	990
Mean (±SD)	14.7 (±6.9)	15 (±6.9)	15.1 (±7.2)	14.9 (±7.0)
PSSD score 0-100, n	411	201	198	810
Symptom score, mean (±SD)	54.2 (±26.1)	53.8 (±26.1)	58.6 (±23.6)	55.1 (±25.6)
Mean sign score (±SD)	56.3 (±22.5)	56.8 (±21.5)	60.9 (±20.2)	57.6 (±21.8)
Psoriatic arthritis, n (%)	89 (17.9)	44 (17.7)	46 (18.5)	179 (18.0)
Prior treatments, n (%)				
Topical agents	477 (96.2)	237 (96.0)	233 (94.0)	947 (95.6)
Phototherapy	293 (59.1)	135 (54.7)	137 (55.2)	565 (57.0)
Conventional systemic agents	331 (66.7)	159 (64.1)	149 (60.1)	639 (64.4)
Biologic agents	101 (20.4)	49 (19.8)	54 (21.8)	204 (20.6)

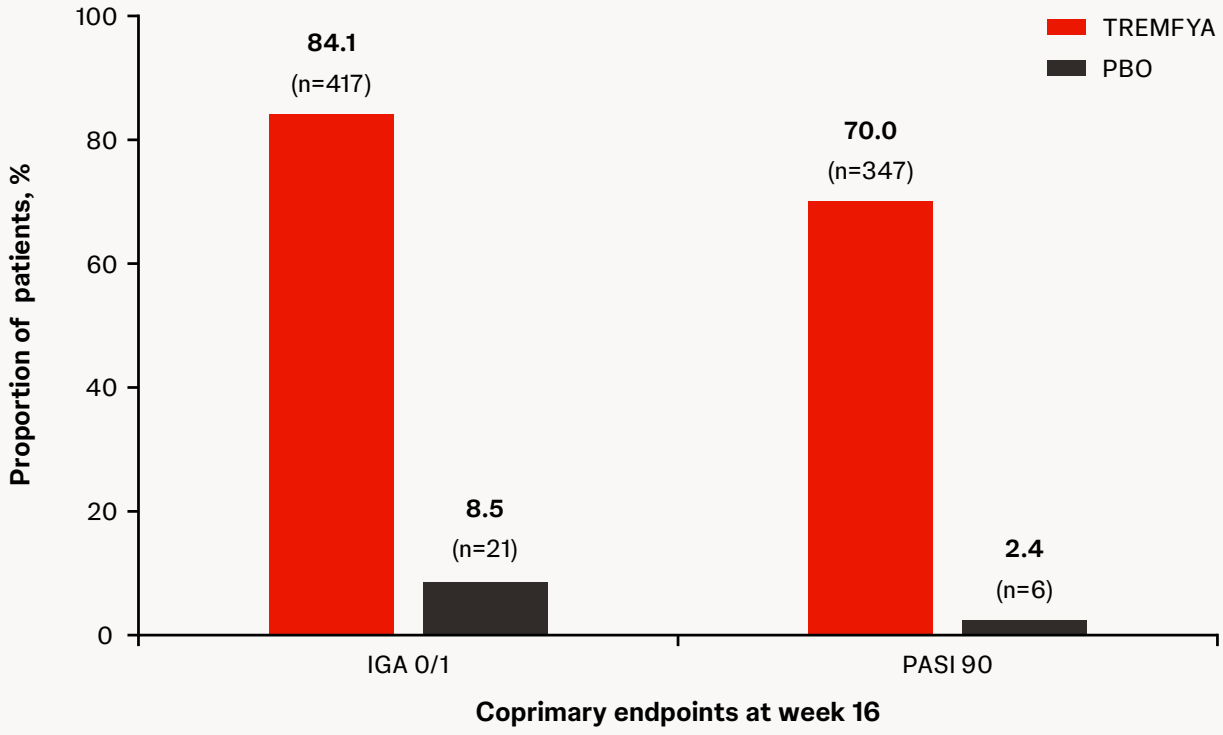
- Treatment discontinuation through week 48 occurred in 9.7% (96 of 992) of patients (TREMFYA 7.9%; PBO 11.7%; ADA 11.3%).[1]

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- At week 16, the coprimary endpoints of IGA score of 0 or 1 and PASI 90 were achieved by significantly more patients in the TREMFYA vs PBO group (*P*<0.001 each).[1]

IGA 0/1 and PASI 90 response rates at week 16[1]



- A significantly higher PASI score % improvement was observed at week 2 in the TREMFYA vs PBO group (*P*<0.001).[1]

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- TREMFYA was superior to PBO and/or ADA for all major secondary endpoints (*P*<0.001 for all).[1]

Efficacy measures and patient-reported outcomes at week 16 and week 24[1]

	TREMFYA 100 mg (N=496)	ADA 40 mg (N=248)	PBO (N=248)
Week 16			
IGA 0/1	84.1%; n=417	67.7%; n=168	8.5%; n=21
PASI 90	70.0%; n=347	46.8%; n=116	2.4%; n=6
PASI 75	86.3%; n=428	68.5%; n=170	8.1%; n=20
Proportion of patients who achieved ss-IGA 0/1[a]	80.6%; n/N=329/408	67.0%; n/N=130/194	10.9%; n/N=22/202
Change from baseline in DLQI score[b]	n=496	n=248	n=248
Mean (±SD)	-11.3 (±6.8)	-9.7 (±6.8)	-2.6 (±6.9)
Change from baseline in PSSD symptom score	n=411	n=201	n=198
Mean (±SD)	-40.4 (±26.5)	-32.8 (±24.9)	-8.3 (±23.7)
Week 24			
IGA 0	51.8%; n=257	31.5%; n=78	-
IGA 0/1	83.5%; n=414	64.9%; n=161	-
PASI 90	75.2%; n=373	54.8%; n=136	-
Proportion of patients who achieved PSSD symptom score 0[c]	35.1%; n/N=144/410	22.5%; n/N=45/200	-

[a]Patients with ss-IGA score ≥2 at baseline.
[b]Patients with DLQI ≥1 at baseline.
[c]Patients with PSSD symptom score ≥1 at baseline.

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Active comparator-controlled period (week 0-24)[1]

- At week 24, significantly higher response rates were maintained in the TREMFYA vs ADA groups for IGA 0 (51.8% vs 31.5%; major secondary endpoint), IGA 0/1 (83.5% vs 64.9%; major secondary endpoint), PASI 90 (75.2% vs 54.8%; major secondary endpoint), and PASI 100 (44.2% vs 26.6%).

Click to see percentage of patients achieving PASI 90, PASI 100, IGA 0/1, or IGA 0 from weeks 0 to 24

Randomized withdrawal and retreatment period (week 28-48)[1]

- PASI 90 was better maintained by the TREMFYA week 28 responders who continued TREMFYA vs those who were rerandomized to PBO.
- Among patients withdrawn from TREMFYA at week 28, PASI 90 rates began to diverge from the maintenance group at week 32.
- The medium time to loss of PASI 90 in patients withdrawn from TREMFYA was 15.2 weeks (23 weeks after the last TREMFYA dose).
- Through week 48, PASI 90 was sustained by 88.6% (171/193) of patients in the maintenance group vs 36.8% (67/182) of patients in the withdrawal group.[6]
- Clinical responses (IGA, PASI) and improvements in DLQI and PSSD symptom or sign scores from baseline were all greater in the maintenance group than in the withdrawal group.
- Through week 48, a small number of patients (n=16) were retreated with TREMFYA due to ≥50% loss of week-28 PASI 90 response.

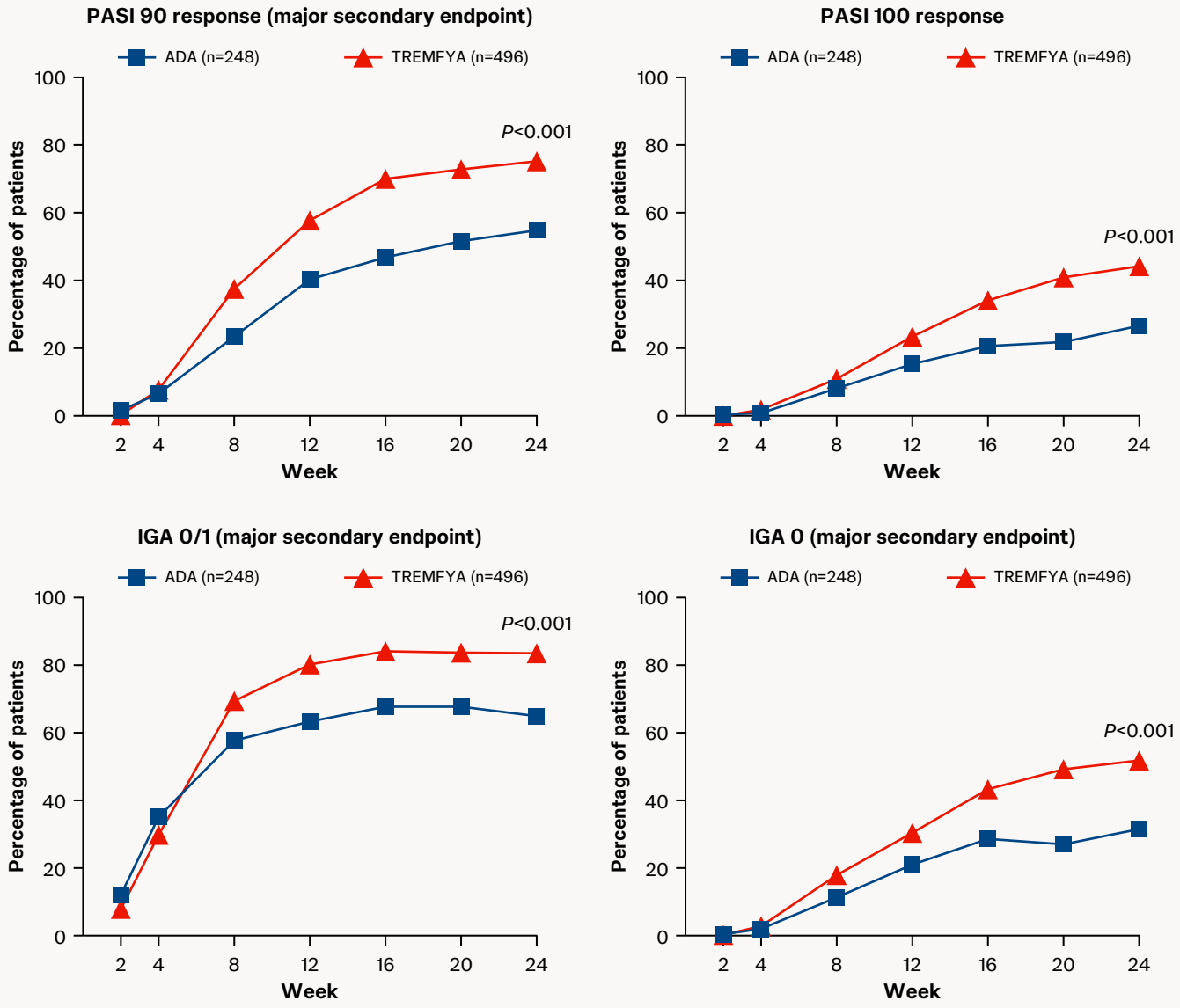
Overall retreatment period (week 28-72 or after week 72)[6]

- Through week 72, PASI 90 was sustained by 86.0% (166/193) of patients in the maintenance group vs 11.5% (21/182) of patients in the withdrawal group.
- Of those patients rerandomized to PBO after having achieved PASI 90 at week 28 with TREMFYA, 87.6% recaptured PASI 90 at 24 or 28 weeks after retreatment with TREMFYA.

Blinded retreatment period (week 28-72)

- This analysis includes retreatment efficacy from the double-blind randomized withdrawal and retreatment period. It includes patients who were retreated or initiated TREMFYA through week 52 (n=53), with efficacy data collected through week 72.[7]
- Through week 72 using TFR, 80.4% of patients regained PASI 90 at 20 weeks after reinitiating treatment,[8] and 96.1% of patients achieved PASI 75 at the same time point.[7]

Percentage of patients achieving PASI 90, PASI 100, IGA 0/1, or IGA 0 from weeks 0 to 24[1]



ADA, adalimumab; IGA 0/1, Investigator's Global Assessment cleared/minimal (IGA 0, cleared; IGA 1, minimal); PASI 90/100, ≥90%, or 100% improvement in Psoriasis Area and Severity Index score from baseline.

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Safety events in the PBO-controlled period (weeks 0-16)[1]

	Weeks 0-16		
	TREMFYA	ADA	PBO
Treated patients, n	494	248	248
Mean duration of follow-up, weeks	16.14	16.07	15.89
≥1 AE, n (%)	235 (47.6)	120 (48.4)	111 (44.8)
Common AEs (occurring in ≥5% of patients in any group), n (%)			
Nasopharyngitis	35 (7.1)	20 (8.1)	16 (6.5)
Headache	25 (5.1)	5 (2.0)	7 (2.8)
Upper respiratory tract infection	16 (3.2)	4 (1.6)	10 (4.0)
Discontinued treatment due to AE, n (%)	7 (1.4)	4 (1.6)	2 (0.8)
≥1 SAE, n (%)	8 (1.6)	6 (2.4)	3 (1.2)
Infections, n (%)	106 (21.5)	58 (23.4)	46 (18.5)
Requiring treatment	35 (7.1)	19 (7.7)	17 (6.9)
Serious infections	1 (0.2)	2 (0.8)	1 (0.4)
Malignancies[a], n (%)	0 (0.0)	0 (0.0)	0 (0.0)
NMSC[b], n (%)	0 (0.0)	0 (0.0)	0 (0.0)
MACE[c], n (%)	0 (0.0)	0 (0.0)	0 (0.0)

[a]Includes malignancies other than NMSC (prostate cancer, n=1).
[b]Includes basal cell and squamous cell carcinomas.
[c]Includes sudden cardiac death, MI, and stroke.

- ISRs occurred in 6.9% of ADA-treated patients vs 2.6% of TREMFYA-treated patients.

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Safety events in the active-comparator period (weeks 0-28)[1]

	Weeks 0-28		Weeks 16-28
	TREMFYA	ADA	PBO→ TREMFYA
Treated patients, n	494	248	233
Mean duration of follow-up, weeks	27.70	27.45	11.95
≥1 AE, n (%)	288 (58.3)	156 (62.9)	78 (33.5)
Common AEs (occurring in ≥5% of patients in any group), n (%)			
Nasopharyngitis	51 (10.3)	34 (13.7)	12 (5.2)
Headache	29 (5.9)	9 (3.6)	5 (2.1)
Upper respiratory tract infection	25 (5.1)	10 (4.0)	5 (2.1)
Discontinued treatment due to AE, n (%)	11 (2.2)	6 (2.4)	1 (0.4)
≥1 SAE, n (%)	18 (3.6)	9 (3.6)	4 (1.7)
Infections, n (%)	153 (31.0)	87 (35.1)	41 (17.6)
Requiring treatment	58 (11.7)	29 (11.7)	19 (8.2)
Serious infections	3 (0.6)	3 (1.2)	1 (0.4)
Malignancies[a], n (%)	1 (0.2)	0 (0.0)	0 (0.0)
NMSC[b], n (%)	1 (0.2)	0 (0.0)	2 (0.9)[5]
MACE[c], n (%)	1 (0.2)	1 (0.4)	0 (0.0)

[a]Includes malignancies other than NMSC (prostate cancer, n=1).
[b]Includes basal cell and squamous cell carcinomas.
[c]Includes sudden cardiac death, MI, and stroke.

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Safety events in the randomized withdrawal and retreatment period (weeks 28-48)[1]

	Weeks 28-48	
	Maintenance group[a]	**Withdrawal group[b]**
Treated patients, n	192	182
Mean duration of follow-up, weeks	20.02	19.47
≥1 AE, n (%)	99 (51.6)	81 (44.5)
Common AEs (occurring in ≥5% of patients in any group), n (%)		
Nasopharyngitis	22 (11.5)	23 (12.6)
Headache	3 (1.6)	2 (1.1)
Upper respiratory tract infection	9 (4.7)	10 (5.5)
Discontinued treatment due to AE, n (%)	0 (0.0)	0 (0.0)
≥1 SAE, n (%)	2 (1.0)	3 (1.6)
Infections, n (%)	55 (28.6)	50 (27.5)
Requiring treatment	23 (12.0)	9 (4.9)
Serious infections	1 (0.5)	0 (0.0)
Malignancies[c], n (%)	0 (0.0)	0 (0.0)
NMSC[d], n (%)	0 (0.0)	0 (0.0)
MACE[e], n (%)	0 (0.0)	0 (0.0)

[a]Includes TREMFYA week-28 PASI 90 responders rerandomized at week 28 to continue TREMFYA 100 mg q8w.
[b]Includes TREMFYA week-28 PASI 90 responders rerandomized at week 28 to PBO (withdrawal), then retreated with TREMFYA 100 mg q8w after 50% or more loss of week-28 PASI 90 response.
[c]Includes malignancies other than NMSC (prostate cancer, n=1).
[d]Includes basal cell and squamous cell carcinomas.
[e]Includes sudden cardiac death, MI, and stroke.

- No AEs were reported among the 16 patients who were retreated.

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Additional safety through week 48[1]:

- One additional NMSC occurred in the PBO→TREMFYA group.[9]
- One additional MACE (MI) was reported in the PBO→TREMFYA group.
- No serious infections, malignancies, or MACE occurred in the ADA→TREMFYA group.
- No deaths, opportunistic infections, hypersensitivities, or anaphylactic reactions occurred through week 48.
- Antibodies to TREMFYA were detected in 6.6% (57/869) of patients through week 48, with generally low titers (88% ≤1:160).
- No association was observed between antibody development and decreased efficacy or ISR development.

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- The VOYAGE 2 OLE evaluated the long-term efficacy (week 252) and safety (week 264) of TREMFYA for the treatment of moderate to severe plaque PsO in patients receiving treatment with TREMFYA through 5 years (week 264).[4,10,11]
- For information regarding the study design of VOYAGE 2, including its OLE, refer to image: VOYAGE 2 Study Design through Week 264.
- For the 5-year OLE analysis, data are presented as defined below[4]:
  - The combined TREMFYA group (n=727) included patients randomized to TREMFYA at baseline and to PBO who crossed-over to receive TREMFYA at week 16.
  - The ADA→TREMFYA group (n=220) included patients randomized to ADA at baseline who crossed over to receive TREMFYA at or after week 28.
- Efficacy endpoints were analyzed up to week 252 using prespecified TFR[4]:
  - TFR defined patients as those with treatment failures if discontinuation occurred due to lack of efficacy, worsening of PsO, or use of a protocol-prohibited PsO treatment.
  - Some patients were retreated with TREMFYA at week 76; thus, efficacy was evaluated for all patients treated with TREMFYA starting at week 100 to allow time for adequate response.
- Safety was assessed through week 264[4,10]:
  - Only events that occurred during treatment with TREMFYA were included.

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- Refer to table: Demographics and Disease Characteristics for VOYAGE 2 baseline patient characteristics.
- The discontinuation rates due to ≥1 AE through 5 years was reported to be 43 (5.9%) and 14 (6.4%) for the combined TREMFYA and ADA→TREMFYA groups, respectively.[4]

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- PASI 90 and PASI 100 responses from week 100 through week 252 are reported in the table: Proportion of Patients Who Achieved PASI 90 or PASI 100 Response.

Proportion of patients who achieved PASI 90 or PASI 100 response (TFR analysis)[4]

	TFR	
	Combined TREMFYA[a]	**ADA→TREMFYA[b]**
Week 100	**n=657**	**n=210**
PASI 90	79.1%	81.4%
PASI 100	48.4%	51.4%
Week 156	**n=613**	**n=201**
PASI 90	77.3%	76.1%
PASI 100	48.9%	49.3%
Week 204	**n=597**	**n=192**
PASI 90	79.6%	76.6%
PASI 100	50.9%	49.0%
Week 252	**n=560**	**n=177**
PASI 90	82.0%	79.1%
PASI 100	53.0%	52.5%

[a]Includes patients randomized to TREMFYA at baseline and to PBO who crossed over and were treated with TREMFYA at week 16.
[b]Includes patients randomized to ADA at baseline who crossed over and were treated with TREMFYA at or after week 28.

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- IGA 0/1 and IGA 0 responses from week 100 through week 252 are reported in the table: Proportion of Patients Who Achieved IGA 0/1 or IGA 0 Scores.

Proportion of patients who achieved IGA 0/1 or IGA 0 scores (TFR analysis)[4]

	TFR	
	Combined TREMFYA[a]	**ADA→TREMFYA[b]**
Week 100	**n=655**	**n=210**
IGA 0/1	83.1%	85.2%
IGA 0	52.7%	54.8%
Week 156	**n=611**	**n=201**
IGA 0/1	83.3%	84.1%
IGA 0	53.0%	50.7%
Week 204	**n=597**	**n=191**
IGA 0/1	81.7%	81.2%
IGA 0	52.6%	51.8%
Week 252	**n=559**	**n=177**
IGA 0/1	85.0%	83.1%
IGA 0	55.5%	54.8%

[a]Includes patients randomized to TREMFYA at baseline and to PBO who crossed over and were treated with TREMFYA at week 16.
[b]Includes patients randomized to ADA at baseline who crossed over and were treated with TREMFYA at or after week 28.

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- At week 100, among patients in the combined TREMFYA group[10]:
  - The proportion of patients achieving DLQI 0/1 was 70.2% (n=645).
  - The proportion of patients achieving a PSSD symptom score of 0 was 35.7% (n=544).
  - The proportion of patients achieving a PSSD sign score of 0 was 22.0% (n=545).
  - Comparable responses were observed in the ADA→TREMFYA group as well.
- At week 252, among patients in the combined TREMFYA and ADA→TREMFYA group[10]:
  - The proportions of patients achieving DLQI 0/1 were 71.1% (n=550) and 69.9% (n=173), respectively.
  - The proportions of patients achieving a PSSD symptom score of 0 were 42.0% (n=460) and 36.6% (n=145), respectively.
  - The proportions of patients achieving a PSSD sign score of 0 were 31.0% (n=461) and 24.1% (n=145), respectively.

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- No new safety signals were identified through week 264 with TREMFYA treatment.[4]
- There were 4 deaths reported through week 204: 1 in the combined TREMFYA group (diabetic coma at week 89), and 3 in the ADA→TREMFYA group (bronchial carcinoma at week 108, MI at week 113, and sudden death at week 193).[12]
- No additional deaths were reported from week 204 through week 264.[4]

Safety events through week 264[4]

	Combined TREMFYA[a]	ADA→ TREMFYA[b]	Both[c]
Treated patients, n	727	220	947
Average duration of follow-up, weeks	223.25	200.25	217.91
≥1 AE, n (%)	624 (85.8)	189 (85.9)	813 (85.9)
Discontinuation due to ≥1 AE, n (%)	43 (5.9)	14 (6.4)	57 (6.0)
≥1 SAE, n (%)	118 (16.2)	34 (15.5)	152 (16.1)
Infections, n (%)	485 (66.7)	151 (68.6)	636 (67.2)
Infections requiring antibiotics	297 (40.9)	83 (37.7)	380 (40.1)
Serious infections	23 (3.2)	5 (2.3)	28 (3.0)
Malignancies, n (%)			
NMSC	7 (1.0)	4 (1.8)	11 (1.2)
Other than NMSC	11 (1.5)	3 (1.4)	14 (1.5)
MACE, n (%)	10 (1.4)	3 (1.4)	13 (1.4)
Deaths, n (%)	1 (0.1)	3 (1.4)	4 (0.4)

[a]Includes patients randomized to TREMFYA at baseline and to PBO who crossed over and were treated with TREMFYA at week 16.
[b]Includes patients randomized to ADA at baseline who crossed over and were treated with TREMFYA at or after week 28.
[c]Includes both combined TREMFYA and ADA→TREMFYA groups, as defined above.

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AE	Adverse event	**PASI 75/90/100**	≥75%, ≥90%, or 100% improvement in Psoriasis Area and Severity Index score from baseline
ADA	Adalimumab	**PSSD**	Psoriasis Symptoms and Signs Diary
BSA	Body surface area	**PBO**	Placebo
BMI	Body mass index	**PsO**	Psoriasis
DBL	Database lock	**q2w**	Every 2 weeks
DLQI	Dermatology Life Quality Index	**q8w**	Every 8 weeks
HRQoL	Health-related quality of life	**R**	Randomization
IGA 0/1	Investigator's Global Assessment cleared/minimal (IGA 0, cleared; IGA 1, minimal)	**res**	responders
ISR	Injection site reactions	**SAE**	Serious adverse event
MI	Myocardial infarction	**SD**	Standard deviation
MACE	Major adverse cardiovascular event	**SE**	Secondary endpoint
NMSC	Nonmelanoma skin cancer	**ss-IGA**	Scalp-specific Investigator's Global Assessment
nonres	nonresponders	**TFR**	Treatment failure rules
OLE	Open-label extension		

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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 25 March 2026.

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