Q2W than PBO attained ACR50, improvement in HAQ-DI ≥ 0.35 , MDA, DAS28-CRP, and DAPSA ≤ 14 . Improvement persisted on all measures through Week 52.

	1-TNFI Inadequate Responder n/N (%)			2-TNFI Inadequate Responder n/N (%)		
	PBO	Q4W	Q2W	PBO	Q4W	Q2W
ACR50						
Week 24	2/68 (2.9%)	24/71 (33.8%)*	19/65 (29.2%)*	3/41 (7.3%)	15/41 (36.6%)*	16/46 (34.8%)*
Week 52	—	29/71 (40.8%)	20/65 (30.8%)	—	18/41 (43.9%)	13/46 (28.3%)
Improvement in HAQ-DI $\geq 0.35^a$						
Week 24	9/61 (14.8%)	28/61 (45.9%)*	19/58 (32.8%)*	7/38 (18.4%)	16/36 (44.4%)*	20/41 (48.8%)*
Week 52	—	32/61 (52.5%)	18/58 (31.0%)	—	14/36 (38.9%)	13/41 (31.7%)
MDA						
Week 24	3/68 (4.4%)	22/71 (31.0%)*	14/65 (21.5%)*	1/41 (2.4%)	8/41 (19.5%)*	13/46 (28.3%)*
Week 52	—	26/71 (36.6%)	17/65 (26.2%)	—	11/41 (26.8%)	7/46 (15.2%)
DAPSA ≤ 14						
Week 24	11/68 (16.2%)	30/71 (42.3%)*	24/65 (36.9%)*	2/41 (4.9%)	14/41 (34.1%)*	12/46 (26.1%)*
Week 52	—	41/71 (57.7%)	26/65 (40.0%)	—	18/41 (43.9%)	14/46 (30.4%)
DAS28-CRP Good Response Criteria ^b						
Week 24	7/68 (10.3%)	33/71 (46.5%)*	24/65 (36.9%)*	2/41 (4.9%)	17/41 (41.5%)*	16/46 (34.8%)*
Week 52	—	38/71 (53.5%)	27/65 (41.5%)	—	19/41 (46.3%)	15/46 (32.6%)

*P<0.05 vs. PBO, **P<0.001 vs. PBO, Fisher's exact test. Missing values imputed using nonresponder imputation.

^aPatients with ≥ 0.35 HAQ-DI at baseline.

^bGood response criteria defined as >1.2 improvement and ≤ 3.2 present DAS28-CRP.

Conclusion: Both IXE Q4W and Q2W improved the signs and symptoms of PsA in a population of difficult-to-treat patients who have had inadequate response to 1 or 2 TNFi.

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OP0111

A RANDOMIZED, PHASE 3, DOUBLE-BLIND TRIAL EXAMINING METHOTREXATE AND ETANERCEPT AS MONOTHERAPY OR IN COMBINATION FOR TREATING PSORIATIC ARTHRITIS: A COMPARISON OF THE COMPOSITE MEASURES USED TO EVALUATE DISEASE ACTIVITY

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Background: Optimal treatment regimens and measuring outcomes in psoriatic arthritis (PsA) remain key areas of research.

Objectives: To examine methotrexate (MTX) and etanercept (ETN) as monotherapy or in combination in a randomized trial and assess the relative performance of PsA-specific composite measures using trial efficacy data.

Methods: Patients with active PsA naïve to biologic drugs (no prior MTX for PsA) were randomized to 3 groups for 48 weeks: ETN 50mg+MTX 20mg weekly (Combo; N=283); ETN 50mg+placebo weekly (ETN-mono; N=284); or MTX 20mg+placebo weekly (MTX-mono; N=284). At week 24, the American College of Rheumatology (ACR)20 and Minimal Disease Activity (MDA) responses were the primary and key secondary endpoints, respectively. Other PsA-specific composite measures used for disease activity included the Psoriatic Arthritis Disease Activity Score (PASDAS) and Disease Activity Index for Psoriatic Arthritis (DAPSA).

Results: Baseline characteristics were well balanced in the 3 arms. Mean (SD) age was 48.4 (13.1) years and mean/median PsA duration 3.2/0.6 years. ACR20 and MDA responses at week 24 were significantly greater with ETN-mono vs MTX-mono and Combo vs MTX-mono; ETN-mono and Combo had similar results (Table). PASDAS also showed differences between each ETN-containing arm vs MTX-mono and no difference for ETN-mono vs Combo, whereas study arm differences were not seen with DAPSA. PASDAS had a greater effect size and standardized response than DAPSA.

Conclusion: In this large randomized, controlled PsA trial, ETN-mono or Combo had greater efficacy than MTX-mono. Combining ETN and MTX did not improve ETN efficacy. Compared with the joint-focused DAPSA, PASDAS captured a wider range of PsA manifestations and performed better in this trial.

	Table: Week 24 Results					
	Methotrexate Monotherapy N=284	Etanercept Monotherapy N=284	Methotrexate+Etanercept N=283			
	Composite endpoint response ^a (SDR)	ES ^b (SDR)	Composite endpoint response ^a (P-value) ^c	ES ^b (SDR)	Composite endpoint response ^a (P-value) ^c	ES ^b (SDR)
ACR 20, %	50.7	—	65.9 (P<0.001)	—	65.5 (P<0.001)	—
ACR 50, %	30.6	—	44.4 (P<0.001)	—	45.7 (P<0.001)	—
ACR 70, %	13.8	—	29.2 (P<0.001)	—	27.7 (P<0.001)	—
MDA, %	22.9	—	35.9 (P<0.001)	—	35.7 (P<0.001)	—
VDA, %	4.8	—	15.2 (P<0.001)	—	14.3 (P<0.001)	—
PASDAS	-1.98 (0.10)	1.56 (1.26)	-2.84 (0.10)	2.26 (1.66)	-2.63 (0.11)	2.15 (1.54)
DAPSA	-22.6 (1.4)	0.92 (1.54)	-25.0 (1.3)	1.06 (1.25)	-24.9 (1.4)	1.06 (1.12)

ACR, American College of Rheumatology; PASDAS, Psoriatic Arthritis Disease Activity Score; SD, standard deviation; SE, standard error; SDR, standardized response; VDA, very low disease activity

^aPercent patients with response for ACR, MDA, and VDA; mean change from baseline (SE) for PASDAS and DAPSA

^bEffect size (baseline mean-post baseline mean)/SD of baseline mean

^cStandardized response (baseline mean-post baseline mean)/SD of change from baseline for that visit, in the same treatment group

^dP-values are for comparison with methotrexate monotherapy; P-values in bold measured statistical significance; all others are unadjusted

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OP0112

UNACCEPTABLE PAIN DESPITE INFLAMMATION CONTROL AFTER START OF A FIRST ANTI-TNF THERAPY IN PATIENTS WITH PSORIATIC ARTHRITIS AND ITS RELATION TO TREATMENT RESPONSE

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Background: Pain is a major concern of patients with inflammatory arthritides, but while considerable focus has been put on the occurrence and