SEAM-PsA EULAR abstract: 3599/3600 characters (includes spaces, author info, and table). Table can have max of 20 rows/12 columns
Submission deadline: 31 Jan 2019 by 2:59pm PST

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.

Conclusions: 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.

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Table: Week 24 Results

	Methotrexate Monotherapy N=284		**Etanercept Monotherapy N=284**		**Methotrexate plus Etanercept N=283**	
	Composite endpoint response[a]	ES[b] (SR[c])	Composite endpoint response[a] (P-value)[d]	ES[b] (SR[c])	Composite endpoint response[a] (P-value)[d]	ES[b] (SR[c])
ACR 20, %	50.7	–	60.9 **(P=0.029)**	–	65.0 **(P=0.005)**	–
ACR 50, %	30.6	–	44.4 (P=0.006)	–	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=0.005)**	–	35.7 **(P=0.005)**	–
VLDA, %	4.8	–	15.2 (P<0.001)	–	14.3 (P<0.001)	–
PASDAS	-1.98 (0.10)	1.56 (1.26)	-2.64 (0.10) (P<0.001)	2.26 (1.66)	-2.63 (0.11) (P<0.001)	2.15 (1.54)
DAPSA	-22.6 (1.4)	0.92 (1.04)	-25.0 (1.3) (P=0.24)	1.08 (1.25)	-24.9 (1.4) (P=0.23)	1.06 (1.12)

ACR, American College of Rheumatology; DAPSA, Disease Activity Index for Psoriatic Arthritis; ES, effect size; MDA, minimal disease activity; PASDAS, Psoriatic Arthritis Disease Activity Score; SD, standard deviation; SE, standard error; SR, standardized response; VLDA, very low disease activity

[a]Percent patients with response for ACR, MDA, VLDA; mean change from baseline (SE) for PASDAS and DAPSA

[b]Effect size=(baseline mean−post baseline mean)/SD of baseline mean

[c]Standardized response=(baseline mean−post baseline mean)/SD of change from baseline for that visit, in the same treatment group

[d]P-values are for comparison with methotrexate monotherapy. P-values in bold had statistical significance; all others are unadjusted