

Abstract SAT0320 – Table 2. Inter-reader reliability and agreement analysis of MASEI components. All items were categorised as yes/no. N/A not applicable since one of the lectors offers the same result for all cases, so kappa can't be calculated in this item due to sparse differences between lectors. N/B enthesis without bursa.

	Abnormal tendon structure	Thickened tendon	Erosion	Enthesis calcification	Enthesis PD	Bursitis
Triceps tendon enthesis	Mean kappa 0.618 ± 0.104 83.95%	0.606 ± 0.103 86.42%	0.808 ± 0.160 95.53%	0.579 ± 0.119 80.25%	0.628 ± 0.193 95.06%	N/B
Quadriceps tendon enthesis	Mean kappa 0.529 ± 0.103 76.55%	0.580 ± 0.100 79.01%	1.000 ± 0.000 100%	0.487 ± 0.115 78.88%	0.610 ± 0.110 82.71%	N/B
Proximal patellar ligament enthesis	Mean kappa 0.507 ± 0.116 77.77%	0.671 ± 0.100 83.95%	0.475 ± 0.181 88.89%	0.230 ± 0.094 58.03%	0.732 ± 0.137 93.83%	N/B
Distal patellar ligament enthesis	Mean kappa 0.258 ± 0.153 80.25%	0.493 ± 0.125 81.48%	1.000 ± 0.000 100%	0.438 ± 0.122 77.77%	0.885 ± 0.069 95.06%	N/A
Achilles tendon enthesis	Mean kappa 0.474 ± 0.106 72.84%	0.784 ± 0.094 91.36%	0.953 ± 0.046 98.77%	0.407 ± 0.146 81.48%	0.812 ± 0.088 92.59%	0.782 ± 0.113 93.83%
Plantar aponeurosis enthesis	Mean kappa 0.427 ± 0.119 72.84%	0.752 ± 0.088 87.04%	1.000 ± 0.000 100%	0.171 ± 0.058 45.68%	N/A	N/B

Conclusions: MASEI has demonstrated to be a reliable tool in PsA. Erosions and PD showed the best reliability values. Evaluating different definitions of enthesis PD, signal in the tendon was the most reliable one, followed with minimal differences by PD MASEI and PD OMERACT, and in last place PD bursa.

Disclosure of Interest: None declared

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SAT0321 IXEKIZUMAB TREATMENT SIGNIFICANTLY IMPROVES ENTHESITIS AND DACTYLITIS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS FROM THE SPIRIT TRIALS

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease with heterogeneous musculoskeletal manifestations including enthesitis and dactylitis. Ixekizumab (IXE), an interleukin-17A antagonist, is approved in the USA for the treatment of PsA including patients with pre-existing enthesitis or dactylitis.

Objectives: To investigate the impact of IXE treatment on the resolution of enthesitis or dactylitis and whether such improvements were associated with improved function and health-related quality of life (HRQoL).

Methods: Patients with active PsA who were biologic-naïve (SPIRIT-P1; NCT01695239) or with prior inadequate response to tumour necrosis factor inhibitor(s) (SPIRIT-P2; NCT02349295) were randomised to placebo (PBO) or 80 mg IXE every 4 weeks (IXEQ4W) or 2 weeks (IXEQ2W), after a 160 mg starting dose. All patients who were inadequate responders at Week 16 received rescue therapy (changes in background therapy). Leeds Enthesitis Index (LEI), Leeds Dactylitis Index-Basic (LDI-B), Health Assessment Questionnaire Disability Index (HAQ-DI), and EuroQoL-5D Visual Analogue Scale (EQ-5D VAS) were measured at Week 24. Missing data or data from inadequate responders were considered non-response or imputed with last observation carried forward for categorical and continuous measures, respectively. Statistical comparisons between PBO and IXE treatment groups were performed with a logistic regression model using Wald's test with treatment and study as factors. In post hoc-analyses, associations between enthesitis and dactylitis with HAQ-DI and EQ-5D VAS are based on an ANCOVA model adjusting for study and Disease Activity of Psoriatic Arthritis (DAPSA).

Results: In the integrated SPIRIT-P1 and -P2 dataset (n=679), 403 patients (59% of total) had baseline enthesitis (LEI >0) with a mean 2.9 LEI score, and 155 patients (23% of total) had baseline dactylitis (LDI-B >0) with a mean 56.4 LDI-B score. Relative to PBO, IXE treatment resulted in significantly higher resolution of enthesitis (SPIRIT-P1) and dactylitis (SPIRIT-P1 and -P2) after 24 weeks.^{1,2} In the integrated SPIRIT-P1 and -P2 dataset, both IXEQ4W and IXEQ2W had significantly higher enthesitis and dactylitis resolution than PBO treatment at Week 24 (Table). In ad-hoc analysis, IXE treatment had significantly higher resolution of enthesitis compared to PBO at the enthesial points comprising the LEI score (Table). For all PBO- and IXE-treated patients at Week 24, least squares mean (SE) HAQ-DI changes from baseline were -0.44 (0.05) and -0.25 (0.03); p<0.01 for patients who did and did not resolve enthesitis, and -0.41 (0.06) and -0.31 (0.07); p=0.34 for patients who did and did not resolve dactylitis. Corresponding EQ-5D VAS improvements were 12.3 (2.2) and 5.8 (1.5); p=0.02 for patients who did and did not resolve enthesitis, and 10.8 (2.8) and 9.8 (3.5); p=0.83 for patients who did and did not resolve dactylitis.

Abstract SAT0321 – Table 1. Enthesitis and Dactylitis Resolution from the Integrated SPIRIT-P1 and SPIRIT-P2 Dataset (Week 24)

	PBO	IXEQ4W	IXEQ2W
LEI=0	26/126 (21%)	53/136 (39%)*	49/141 (35%)*
Lateral epicondyle=0	24/79 (30%)	39/85 (46%)*	39/86 (45%)*
Medial femoral condyle=0	23/79 (29%)	41/92 (45%)*	45/100 (45%)*
Achilles tendon insertion=0	19/64 (30%)	37/75 (49%)*	38/74 (51%)*
LDI-B=0	10/42 (24%)	52/67 (78%)**	30/46 (65%)**

Data presented as n/N (%). N=patients with baseline enthesitis (LEI>0), depicted enthesial points, or dactylitis (LDI-B>0); n=responding patients. *p<0.05,**p<0.01

Conclusions: Treatment with IXE resulted in significant improvement in enthesitis and dactylitis in patients with pre-existing enthesitis or dactylitis. Resolution of enthesitis symptoms was associated with improvements in patients' function and HRQoL.

REFERENCES:

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SAT0322 THE EFFECT OF GUSELKUMAB ON DACTYLITIS: RESULTS FROM A PHASE 2 STUDY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: In a Phase 2 study, Guselkumab (GUS) was shown to be safe and effective in patients (pts) w/active psoriatic arthritis (PsA).

Objectives: To evaluate the effect of GUS on dactylitis in a subset of pts w/dactylitis at baseline (BL) in the phase 2 PsA study of GUS.

Methods: Pts w/active PsA and ≥3% body surface area of plaque psoriasis, despite current or previous treatment, were randomised 2:1 to receive 100 mg subcutaneous GUS at wks 0, 4 then every 8 weeks (wks, q8w) or placebo (PBO) during a 24wk double-blind treatment period. At wk16, pts w/<5% improvement in swollen and tender joint counts early escaped (EE). At wk24, the PBO group crossed over to receive GUS (wks 24, 28 then q8w) (PBO→GUS) and the GUS group continued receiving GUS (GUS→GUS) through wk44. Dactylitis was assessed by scoring each digit from 0–3 (0=absent, 1=mild, 2=moderate, 3=severe), for a combined score of 0–60. Sensitivity analysis of change from BL through wk24 in dactylitic digits was performed (combined score 20). Dactylitis scores during the 24-wk double-blind treatment was analysed using LOCF imputation for missing data and EE. Dactylitis after wk24 was evaluated using observed data.

Results: Of 149 pts, 81 presented w/dactylitis at BL (PBO n=23, mean[SD]=3.9 [3.01]; GUS n=58, mean[SD]=6.5 [6.15]) and 66 continued to the active treatment period (PBO→GUS n=16; GUS→GUS n=50). The dactylitis subset was similar to the overall population in BL characteristics except for higher median values for # of swollen joints, # of tender joints, and CRP. At wks 16 and 24, the GUS group had a significantly greater reduction in the dactylitis score (wk24 mean [SD] change from BL, PBO: -0.4 [6.06]; GUS: -3.8 [4.93]; p=0.006) and a greater% of pts w/dactylitis resolution, compared to the PBO group (figure 1). Consistent results were obtained w/the # digits w/dactylitis (wk24 mean [SD] change from BL, PBO: -0.2 [3.04]; GUS: -2.1 [2.21]; p=0.003). Improvement in dactylitis seen at wk24 was maintained in the GUS→GUS group (wk56: mean[SD] change from BL=-5.5 [4.84], 75% of pts w/resolution) and the values for the PBO→GUS group (wk56: mean[SD] change from BL=-4.4 [3.50], 93.7% of pts w/resolution) approached those of the GUS→GUS group. Improvement in dactylitis was greater in ACR20/ACR50 responders vs non-responders in GUS-treated patients (Table