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POS0197 RESPONSIVENESS OF ULTRASOUND SYNOVITIS AND CLINICAL OUTCOMES IN PSORIATIC ARTHRITIS TREATED WITH SECUKINUMAB: DATA FROM THE ULTIMATE TRIAL

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Background: Power Doppler ultrasonography is a sensitive imaging tool to assess synovitis in psoriatic arthritis (PsA).[1,2] ULTIMATE (NCT02662985) is the first large, randomised, double-blind placebo-controlled phase IIIb study in PsA, using ultrasound to evaluate early response to secukinumab on synovitis. The use of the standardised and reliable global EULAR-OMERACT composite ultrasound synovitis score at patient level (GLOESS) as the primary endpoint showed the early and significant benefit of secukinumab vs. placebo on synovitis at week 12.[3]

Objectives: To investigate the responsiveness and discriminative validity of GLOESS compared to clinical outcomes on joints at week 12 and report ultrasound and clinical efficacy data up to week 24.

Methods: This is a 52-week study with a 12-week double-blind, placebo-controlled period followed by 12-week open-label (OL) and 6-month OL extension. All placebo patients were switched to secukinumab (300 or 150 mg) at week 12.[3] Discriminative validity of GLOESS was analysed post-hoc: within-group responsiveness was assessed by comparing its standardised response mean (SRM) to that of core set of ACR response in the initial secukinumab group over 12 and 24 weeks. Mean change from baseline up to week 12 of GLOESS was determined with mixed-effect model repeated measures analysis (MMRM) and from week 12-24 as observed. 24 week efficacy outcomes included ACR responses, HAQ-DI, PASI response and resolution of dactylitis. These outcomes were exploratory and reported either according to non-responder imputation (ACR response), or as observed (HAQ-DI, PASI response and resolution of dactylitis).

Results: Of 166 patients enrolled, a total of 155 patients (93%) completed 24 weeks of treatment (secukinumab, 79 patients 95%; placebo, 76 patients 92%). Mean change from baseline to week 24 in GLOESS was similar in the initial secukinumab and placebo-secukinumab groups. A continued improvement in GLOESS was observed in the secukinumab group, with catch-up improvement in the placebo group after switch to active therapy (Figure 1). Both SRM of GLOESS and ACR core components over 12 and 24 weeks were high (Table 1). Similar clinical response rates were reported for clinical joint count, skin, dactylitis and function at week 24 in secukinumab and placebo switchers groups (Table 1).

Conclusion: These analyses highlight the responsiveness and high discriminative validity of GLOESS in PsA, resembling that of key clinical PsA manifestations and physical function.

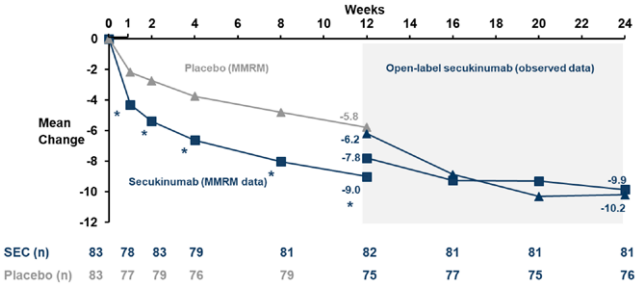

Figure 1. Mean change from baseline in GLOESS by treatment through Week 24

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Table 1. Responsiveness of GLOESS - analysed by standardised response mean and efficacy outcomes at week 24

Standardised response mean (Initial secukinumab)			Efficacy of secukinumab		
	Week 0–12 (N = 83)	Week 0–24 (N = 83)	Responders (%)	Secukinumab week 0–24 (N = 83)	Placebo switchers week 12–24 (N = 83)
GLOESS	1.05	1.06	ACR20	87	74
Tender joint count	1.03	1.35	ACR50	64	49
Swollen joint count	0.91	1.18	ACR70	34	23
Patient global assessment of disease activity	1.37	1.55	HAQ-DI*	80	63
Physician global assessment of disease activity	1.59	2.39	PASI 75†	72	59
Pain	1.32	1.53	PASI 90†	62	45
HAQ-DI score	1.32	1.32	Resolution of dactylitis (LDI=0)	67	59

*HAQ-DI response is defined as an improvement of at least 0.35 score points compared to baseline (change ≤ –0.35)†N value for PASI response in secukinumab and placebo groups are 36 and 33; respectively. PASI response was calculated for patients with BSA ≥ 3 %.BSA, Body Surface Area; LDI, Leeds Dactylitis Index

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POS0198 EFFICACY AND SAFETY OF DEUCRAVACITINIB, AN ORAL, SELECTIVE TYROSINE KINASE 2 INHIBITOR, IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS FROM A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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