were re-randomised to IXEQ2W or IXEQ4W. The primary objective was ACR20 at Wk 24, and an extension from Wks 24 to 156 is on-going. In this analysis, efficacy was assessed at Wk 52 for the intent-to-treat (ITT) population of pts randomised to IXE at Wk 0 by Nail Psoriasis Severity Index (NAPSI) scores in pts with baseline fingernail psoriasis (IXEQ4W, n=89; IXEQ2W, n=74), PASI 75/90/100 response rates in pts with baseline BSA ≥3 (IXEQ4W, n=68; IXEQ2W, n=68), and the rate of Static Physician Global Assessment (sPGA) of psoriasis scores of 0 or 1 (0=cleared, 1=minimal) in pts with baseline sPGA ≥3 (IXEQ4W, n=60, IXEQ2W, n=62). For categorical variables, nonresponder imputation was used for missing data. Percent change from baseline was calculated using modified baseline observation carried forward.

Results: At Wk 52, NAPSI total score (observed cases; mean (SD)) was 5.0 (12.7), 4.4 (7.6), IXEQ4W, IXEQ2W, respectively, with a mean percent change from baseline of −15.2 (19.7),–14.4 (19.0), IXEQ4W, IXEQ2W, respectively. The percentage of pts achieving a NAPSI score of 0 (0=cleared) was 46.1% (n=41), 32.4% (n=24), IXEQ4W, IXEQ2W, respectively. The percentage of pts achieving PASI responses was 60.3% (n=41), 54.4% (n=37) for PASI 75; 50.0% (n=34), 39.7% (n=27) for PASI 90; and 39.7% (n=27), 35.3% (n=24) for PASI 100, IXEQ4W, IXEQ2W, respectively. The percentage of pts achieving sPGA 0 or 1 was 61.7% (n=37), 66.1% (n=41), IXEQ4W, IXEQ2W, respectively. Safety was consistent with the larger study population.

Conclusions: In patients with active PsA, an inadequate response to TNF-inhibitors, and baseline fingernail or skin lesions, treatment with ixekizumab resulted in persistent[1] reduction and clearance of nail and skin lesions after 1 year.

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THU0314 IXEKIZUMAB MAKES VERY LOW DISEASE ACTIVITY AND REMISSION WITH PSORIATIC ARTHRITIS DISEASE ACTIVITY SCORE POSSIBLE IN ACTIVE PSORIATIC ARTHRITIS PATIENTS FOR UP TO 1 YEAR: SPIRIT-P1 AND SPIRIT-P2 TRIALS

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Background: Treatment goals in psoriatic arthritis (PsA) are moving toward attainment of absolute therapeutic thresholds rather than relative improvement. Minimal disease activity (MDA) and very low disease activity (VLDA); Disease Activity in Psoriatic Arthritis (DAPSA) LDA and DAPSA Remission; and Psoriatic Arthritis Disease Activity Score (PASDAS) LDA and PASDAS VLDA are validated composite indices used to measure disease activity states in PsA.

Objectives: The effect of ixekizumab (IXE), as assessed by composite endpoints that incorporate multiple disease domains, was explored up to 52 weeks for the SPIRIT-P1[1] and SPIRIT-P2[2] trials.

Methods: Data were analysed from 2 double-blind, phase III SPIRIT trials investigating the efficacy and safety of IXE, a high-affinity monoclonal antibody selectively targeting interleukin-17A, for patients with active PsA. For SPIRIT-1 (NCT01695239), patients who were biologic disease-modifying antirheumatic drug (DMARD)-naive were randomised to placebo (n=106) or 80 mg IXE every 4 weeks (Q4W, n=107) or every 2 weeks (Q2W, n=103) after a 160 mg starting dose. For SPIRIT-2 (NCT02349295), patients who had an inadequate response or were intolerant to tumour necrosis factor inhibitors (TNFi) were randomised to placebo (n=118) or 80 mg IXE every 4 weeks (Q4W, n=122) or every 2 weeks (Q2W, n=123) after a 160 mg starting dose. MDA, MDA VLDA, DAPSA LDA, DAPSA Remission, PASDAS LDA, and PASDAS VLDA composite endpoints were evaluated. Imputation for categorical responses was non-responder imputation. Treatment comparisons (with respect to placebo up to Week 24) based on the intent-to-treat population were made using a logistic regression model. Data up to Week 52 are summarised descriptively.

Results: The therapeutic threshold results are summarised in table 1. At Week 24, the percentage of patients achieving MDA, MDA VLDA, DAPSA LDA, DAPSA Remission, PASDAS LDA, and PASDAS VLDA was greater with IXE Q4W and IXE Q2W compared with placebo. In patients who continued treatment with IXE through Week 52, response rates of these therapeutic thresholds were either sustained or further improved.

Abstract THU0314 – Table 1. Summary of MDA, DAPSA, and PASDAS Composite Endpoints (NRI) for the SPIRIT-1 and SPIRIT-2 Trails (ITT Population)

	SPIRIT-1[a]					SPIRIT-2				
	PBO (*n* = 106)	IXE Q4W (*n* = 107)	Diff (95% CI[b]) *P* Value[c]	IXE Q2W (*n* = 103)	Diff (95% CI[b]) *P* Value[c]	PBO (*n* = 118)	IXE Q4W (*n* = 122)	Diff (95% CI[b]) *P* Value[c]	IXE Q2W (*n* = 123)	Diff (95% CI[b]) *P* Value[c]
MDA[d], n (%)										
Week 24	16 (15.1)	32 (29.9)	14.8 (3.8, 25.8) 0.010	42 (40.8)	25.7 (14.0, 37.4) <0.001	4 (3.4)	34 (27.9)	24.5 (15.9, 33.1) <0.001	29 (31.9)	20.2 (12.0, 28.4) <0.001
Week 52	NA	42 (39.3)	NA	38 (36.9)	NA	NA	42 (34.4)	NA	29 (23.6)	NA
MDA VLDA[e] (7/7), n (%)										
Week 24	1 (0.9)	11 (10.3)	9.3 (3.3, 15.4) 0.019	12 (11.7)	10.7 (4.2, 17.2) 0.013	1 (0.8)	15 (12.3)	11.4 (5.4, 17.5) 0.006	4 (3.3)	2.4 (-1.1, 5.9) NA
Week 52	NA	15 (14.0)	NA	16 (15.5)	NA	NA	15 (12.3)	NA	8 (6.5)	NA
DAPSA LDA, n (%)										
Week 24	19 (17.9)	34 (31.8)	13.9 (2.4, 25.3) 0.019	35 (34.0)	16.1 (4.4, 27.8) 0.007	13 (11.1)	31 (25.4)	14.4 (4.8, 24.0) 0.005	34 (27.6)	16.6 (6.9, 26.3) 0.001
Week 52	NA	33 (30.8)	NA	30 (29.1)	NA	NA	42 (34.4)	NA	32 (26.0)	NA
DAPSA Remission[f], n (%)										
Week 24	5 (4.7)	17 (15.9)	11.2 (3.2, 19.2) 0.013	25 (24.3)	19.6 (10.3, 28.8) <0.001	1 (0.8)	18 (14.8)	13.9 (7.4, 20.4) 0.003	9 (7.3)	6.5 (1.6, 11.4) 0.039
Week 52	NA	24 (22.4)	NA	30 (29.1)	NA	NA	23 (18.9)	NA	14 (11.4)	NA
PASDAS LDA[g], n (%)										
Week 24	20 (18.9)	45 (42.1)	23.2 (11.2, 35.1) <0.001	52 (50.5)	31.6 (19.4, 43.8) <0.001	8 (6.8)	48 (39.3)	32.6 (22.8, 42.3) <0.001	43 (35.0)	28.2 (18.6, 37.8) <0.001
Week 52	NA	46 (43.0)	NA	52 (50.5)	NA	NA	55 (45.1)	NA	38 (30.9)	NA
PASDAS VLDA[h], n (%)										
Week 24	2 (1.9)	12 (11.2)	9.3 (2.8, 15.8) 0.016	21 (20.4)	18.5 (10.3, 26.7) <0.001	0 (0.0)	16 (13.1)	13.1 (7.1, 19.1) <0.001	9 (7.3)	7.3 (2.7, 11.9) 0.003
Week 52	NA	19 (17.8)	NA	27 (26.2)	NA	NA	21 (17.2)	NA	14 (11.4)	NA

Abbreviations: CI, confidence interval; DAPSA, Disease Activity in Psoriatic Arthritis; Diff, difference; ITT, intent-to-treat; IXE Q2W, ixekizumab 80 mg every 2 weeks; IXE Q4W, ixekizumab 80 mg every 4 weeks; LDA, low disease activity; MDA, minimal disease activity; NA, not available; NRI, non-responder imputation; PASDAS, Psoriatic Arthritis Disease Activity Score; PBO, placebo; VLDA, very low disease activity. [a]Data for adalimumab active comparator arm in SPIRIT-1 trial not shown. [b]CIs are constructed using the simple asymptotic method, without continuity correction (normal approximation to the binomial distribution). [c]*P* values are from a logistic regression model using Wald's test with treatment, geographic region, and baseline conventional disease-modifying antirheumatic drug experience as factors. [d]*P* values are from a logistic regression model using Wald's test with treatment, geographic region, and tumor necrosis factor inhibitor experience as factors. [e]MDA was achieved if 25 of 7 criteria were met and VLDA was achieved if 7 of 7 criteria were met: tender joint count ≤1; swollen joint count ≤1; Psoriasis Area and Severity Index total score ≤1 or body surface area ≤3%; patient's assessment of pain visual analog scale (VAS) ≤15; patient's global assessment of disease activity VAS ≤20; Health Assessment Questionnaire Disability Index ≤0.5; and tender entheseal points ≤1 (assessed by the Leeds Enthesitis Index). [f]DAPSA LDA was defined as DAPSA score ≤4 and ≤14. [g]DAPSA Remission was defined as DAPSA score ≤4. [h]PASDAS LDA was defined as PASDAS ≤3.2; PASDAS VLDA was defined as PASDAS ≤1.9.

Conclusions: Regardless of previous TNFi exposure, in patients with active PsA, a higher proportion of IXE-treated compared with placebo-treated patients achieved MDA and MDA VLDA, DAPSA LDA and DAPSA Remission, and PASDAS LDA and PASDAS VLDA at Week 24. At Week 52, the extent of IXE clinical response was sustained or further improved.

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THU0315 PATIENT-PERCEIVED INVOLVEMENT IN DISEASE MANAGEMENT DRIVES PATIENT-PHYSICIAN ALIGNMENT IN SATISFACTION WITH DISEASE CONTROL IN PSORIATIC ARTHRITIS

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Background: Previous analyses have indicated misalignment between Psoriatic Arthritis (PsA) patients and their physicians can be frequent, and can result in worse disease severity and health-related quality of life[1,2]. Factors associated with this misalignment have not been determined.

Objectives: To assess patient-physician misalignment regarding satisfaction with PsA disease control and identify factors associated with this misalignment.

Methods: Data were drawn from the Adelphi PsA Disease Specific Programme, a real-world survey conducted in 2015 across the US, France, Germany, Italy, Spain, UK. Patients had physician-confirmed PsA and had to have been receiving their current synthetic-DMARD (biologic naïve) or biologic therapy for at least 6 months.