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 persistent¹ reduction and clearance of nail and skin lesions after 1 year.

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Disclosure of Interest: J. F. Merola Consultant for: Merck Research Laboratories, AbbVie, Eli Lilly and Company, Novartis, Janssen, UCB, Sumamed, Celgene, Sanofi Regeneron, and GSK, Speakers bureau: AbbVie, P. Rich Grant/ research support from: AbbVie, Allergan, Anacor Pharmaceuticals, Boehringer Ingelheim, Cassiopea SpA, Dermira, Eli Lilly and Company, Galderma Laboratories, Janssen-Ortho, Kadmon Corporation, Leo Pharma, Merck, Moberg Derma, Novartis, Pfizer, Ranbaxy Laboratories Limited, Sandoz, Viamet, Cellcept, Cutanea, J. P. Dutz Grant/research support from: AbbVie, Novartis, Amgen, Consultant for: CIPHER, Eli Lilly and Company, Speakers bureau: Janssen, AbbVie, Novartis, Amgen, Leo Pharma, Celgene, D. Adams Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, L. Kerr Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, L. E. Kristensen Grant/ research support from: UCB, Biogen, Janssen Pharmaceuticals, Novartis, Speakers bureau: Pfizer, AbbVie, Amgen, UCB, Bristol-Myers Squibb, Biogen, MSD, Novartis, Eli Lilly and Company, Janssen Pharmaceuticals.

DOI: 10.1136/annrheumdis-2018-eular.2347

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-P1¹ and SPIRIT-P2² 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)-naïve 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 Trials (ITT Population)

	SPIRIT-1 ¹					SPIRIT-2				
	PBO (n=106)	IXE Q4W (n=107)	IXE Q2W (n=103)	IXE Q2W (n=103)	IXE Q2W (n=103)	PBO (n=118)	IXE Q4W (n=122)	IXE Q2W (n=123)	IXE Q2W (n=123)	IXE Q2W (n=123)
MDA ¹ n (%)										
Week 24	16 (15.1)	32 (29.9)	14.8 (3.8, 25.8)	42 (40.8)	25.7 (14.0, 37.4)	4 (3.4)	34 (27.9)	24.5 (15.9, 33.1)	29 (31.9)	20.2 (12.0, 28.4)
Week 52	NA	42 (39.3)	NA	38 (36.9)	NA	NA	42 (34.4)	NA	29 (23.6)	NA
MDA VLDA ¹ n (%)										
Week 24	1 (0.9)	11 (10.3)	9.3 (3.3, 15.4)	12 (11.7)	10.7 (4.2, 17.2)	1 (0.8)	15 (12.3)	11.4 (5.4, 17.5)	4 (3.3)	2.4 (-1.1, 5.9)
Week 52	NA	15 (14.0)	NA	16 (15.5)	NA	NA	15 (12.3)	NA	8 (6.5)	NA
DAPSA LDA ¹ n (%)										
Week 24	19 (17.9)	34 (31.8)	13.9 (2.4, 25.3)	35 (34.0)	16.1 (4.4, 27.8)	13 (11.1)	31 (25.4)	14.4 (4.8, 24.0)	34 (27.6)	16.6 (6.9, 26.3)
Week 52	NA	33 (30.6)	NA	30 (29.1)	NA	NA	42 (34.4)	NA	32 (26.0)	NA
DAPSA Remission ¹ n (%)										
Week 24	5 (4.7)	17 (15.9)	11.2 (3.2, 19.2)	25 (24.3)	19.6 (10.3, 28.8)	1 (0.8)	18 (14.8)	13.9 (7.4, 20.4)	9 (7.3)	6.5 (1.6, 11.4)
Week 52	NA	24 (22.4)	NA	30 (29.1)	NA	NA	23 (18.9)	NA	14 (11.4)	NA
PASDAS LDA ¹ n (%)										
Week 24	20 (18.9)	45 (42.1)	23.2 (11.2, 35.1)	52 (50.5)	31.6 (19.4, 43.8)	8 (6.6)	48 (39.3)	32.6 (22.8, 42.3)	43 (35.0)	28.2 (18.6, 37.8)
Week 52	NA	46 (43.0)	NA	52 (50.5)	NA	NA	55 (45.1)	NA	38 (30.9)	NA
PASDAS VLDA ¹ n (%)										
Week 24	2 (1.9)	12 (11.2)	9.3 (2.8, 15.8)	21 (20.4)	18.5 (10.3, 26.7)	0 (0.0)	16 (13.1)	13.1 (7.1, 19.1)	9 (7.3)	7.3 (2.7, 11.9)
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; DMARD, disease-modifying antirheumatic drug; Ixekizumab 80mg every 2 weeks; Ixekizumab 80mg 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. ¹One for at least one active component are in SPIRIT-1 total score. ²One for at least one active component are in SPIRIT-2 total score. ³Values are from a logistic regression model using Wald's test with treatment, geographic region, and baseline conventional disease-modifying antirheumatic drug exposure as factors. ⁴P-values are from a logistic regression model using Wald's test with treatment, geographic region, and tumor necrosis factor inhibitor exposure as factors. MDA was achieved if 5 of 7 criteria were met and VLDA was achieved if 7 of 7 criteria were met (joint count ≤1, swollen joint count ≤1, Psoriasis Area and Severity Index total score ≤5, or body surface area ≥10% patient's assessment of pain-visual analog scale (VAS) ≤25, patient's global assessment of disease activity VAS ≤25, Health Assessment Questionnaire Disability Index ≤5, and tender enthral points ≤1 (assessed by the Leeds Enthalps Index)). DAPSA LDA was defined as DAPSA score ≤4 and DAPSA Remission was defined as DAPSA score ≤4. PASDAS LDA was defined as PASDAS score ≤3. PASDAS VLDA was defined as PASDAS score ≤3.

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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Disclosure of Interest: L. Coates Grant/research support from: AbbVie, Janssen, Consultant for: AbbVie, Celgene, Janssen, Sun Pharma, Pfizer, UCB, MSD, Novartis, Eli Lilly and Company, Amgen, BMS, M. E. Husni Consultant for: AbbVie, Bristol-Myers Squibb, Pfizer, UCB, Novartis, Eli Lilly and Company, Janssen, Genentech, E. Lespessailles Grant/research support from: Novartis, Eli Lilly and Company, Servier, Amgen, Speakers bureau: Novartis, Eli Lilly and Company, L. Kerr Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, G. Gallo Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company

DOI: 10.1136/annrheumdis-2018-eular.2329

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.

Physicians and patients independently provided information on satisfaction with disease control on a 5-point scale (very satisfied/satisfied/neither/dissatisfied/very dissatisfied). Physician and patient reports of satisfaction were compared to assess levels of misalignment. Physicians also provided information on demographics and disease history/severity. Patients provided information on involvement in treatment decisions, EuroQol-5D Visual Analogue Scale (EQ-5D), Work Productivity and Activity Impairment (WPAI) and Health Assessment Questionnaire Disability Index (HAQ-DI). Factors associated with misalignment were analysed by a multivariate logistic regression modelled using predictors identified as significant in univariate logistic regression. Data entered in the analyses included demographics, time diagnosed, treatment history, disease severity, flaring, pain, patient-reported involvement in treatment decisions, EQ-5D, WPAI, HAQ-DI.

Results: 519 physicians (331 rheums, 188 derms) provided data for 2467 PsA patients, 656 meeting all inclusion criteria. Mean age was 49.9 (SD 12.1) years, mean disease duration 6.7 (6.2) years, 53.8% patients were male and 66.1% employed. Satisfaction with disease control was generally high amongst both patients (78.3%) and physicians (91.9%) with alignment in 79.4% of cases. In 16.8% of cases there was misalignment where patients were dissatisfied but physicians satisfied.

Multivariate logistic regression showed that worse HAQ-DI (OR [95% CI]: 0.54 [0.38–0.77], $p=0.001$), worse EQ-VAS (OR 1.03 [1.02–1.04], $p<0.001$), lack of involvement in treatment decisions (OR 1.26 [1.07–1.50], $p=0.007$) and physician-reported severe disease as opposed to mild (OR 0.20 [0.05–0.78], $p=0.020$) were all independently associated with misalignment.

Conclusions: Satisfaction with disease control was generally high for both patients and physicians; however, misalignment was not rare. Patients had higher levels of symptoms/increased impact on activities where there was misalignment. An independent factor associated with misalignment was patient-perceived involvement in condition management. Improving patient-physician engagement in overall disease management may lead to greater patient satisfaction and patient-physician alignment.

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Disclosure of Interest: L. Gossec Grant/research support from: UCB, Lilly, Pfizer, BMS, Consultant for: AbbVie, BMS, Celgene, Janssen, Novartis, Pfizer, Roche UCB, A.-M. Orbai Grant/research support from: AbbVie, Celgene, Eli Lilly, Horizon, Janssen, Novartis, Pfizer, Consultant for: Eli Lilly, Janssen, Novartis, Pfizer, UCB, S. Lobosco Employee of: Adelphi Real World, R. Moon Employee of: Adelphi Real World, O. Massey Employee of: Adelphi Real World, J. Piercy Employee of: Adelphi Real World, J. Cappelleri Shareholder of: Pfizer, Employee of: Pfizer, L. Fallon Shareholder of: Pfizer, Employee of: Pfizer, P. Young Employee of: Pfizer, A. Romero Employee of: Pfizer, M.-A. Hsu Shareholder of: Pfizer, Employee of: Pfizer

DOI: 10.1136/annrheumdis-2018-eular.3057

THU0316

GENDER DIFFERENCES IN BIOLOGIC TREATMENT OUTCOMES – A STUDY OF 1750 PATIENTS WITH PSORIATIC ARTHRITIS USING DANISH HEALTH CARE REGISTERS

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Background: Previous studies have shown conflicting findings on the impact of gender on effectiveness of tumour necrosis factor alpha inhibitor (TNFi) treatment in patients with psoriatic arthritis (PsA).

Objectives: To investigate gender differences in disease manifestations, patient-reported outcomes, comorbidities and treatment effectiveness among patients with PsA treated with their first TNFi

Methods: In this observational cohort study, the nationwide DANBIO register provided prospectively collected data on disease activity and treatment outcomes for PsA patients who initiated their first TNFi in 2000–2015. Data on comorbidities, diagnosed in hospital departments, were obtained by cross-linkage to the Danish National Patient Register. Treatment response was evaluated according to EULAR and ACR criteria at 3- and 6 months. Cox- and logistic regression models analysed the impact of gender on TNFi persistence and response, respectively, while adjusting for a priori selected confounders including clinical-, laboratory- and patient-reported factors, comorbidities and lifestyle characteristics

Results: A total of 1750 PsA patients (53% females) were included. At baseline, women were older (49 years/47 years), more often smokers (32%/26%), had worse patient-reported scores (e.g. global score 71 mm/65 mm) and higher frequencies of hospital-diagnosed anxiety or depression (7%/4%) and chronic pulmonary disease (7%/3%), than men (all $p<0.01$). Median TNFi persistence was 3.8 years (95% CI 3.0–5.7) in men versus 1.4 (1.1–1.8) in women ($p<0.001$), figure 1. Men had higher odds of achieving response according to all response criteria, e.g. adjusted odds ratio=3.2 (1.6–6.1) for EULAR good/moderate response at 6 months (vs. women).

FIGURE: KAPLAN MEIER PLOTS

Abstract THU0316 – Figure 1. Kaplan meier plots

Conclusions: Male patients had better TNFi treatment outcomes. Adjustment for baseline risk factors including patient-reported outcomes, disease activity, comorbidities and lifestyle factors did not influence this relationship, which suggests a role of biological factors.

Acknowledgements: Thanks to patient-research partner Åse Stampe, to all patients and clinicians reporting to DANBIO, and to statistician Peder Frederiksen and biostatistician Robin Christensen for methodological and statistical advices. Thanks to the Oak Foundation, Danish Rheumatism Association, and Department of Rheumatology at Rigshospitalet, Gentofte.

Disclosure of Interest: P. Højgaard Speakers bureau: Celgene and UCB, C. Ballegaard Speakers bureau: Janssen Pharmaceuticals, R. Cordtz: None declared, K. Zobbe: None declared, M. Clausen: None declared, L. Kristensen: None declared, B. Glinthorp Grant/research support from: Abbvie, Biogen, Pfizer, L. Dreyer Speakers bureau: UCB and MSD

DOI: 10.1136/annrheumdis-2018-eular.2923

THU0317

CREATING A EUROPEAN DATABASE OF PSORIATIC ARTHRITIS PATIENTS TREATED IN ROUTINE CARE – FIRST, PRELIMINARY RESULTS FROM THE EUROSPA RESEARCH NETWORK COLLABORATION

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Background: A research network collaboration of 15 European registries collecting data on patients with spondyloarthritis (SpA), "EuroSpA", has recently been created to strengthen research capabilities in the real world setting¹. Here we present initial findings from the collaboration.

Objectives: To investigate the feasibility of creating a common database within the EuroSpA collaboration and to conduct proof-of-concept analyses by investigation of baseline characteristics, disease activity at baseline and after 6 months and 12 months' TNFi retention rate in patients with psoriatic arthritis (PsA) initiating Tumour Necrosis Factor inhibitors (TNFi).