Conclusions: Although pts with BLE had more severe BL clinical characteristics than pts with No BLE, SEC showed higher efficacy than PBO at Wk 16 and sustained efficacy over 104 wks in both groups with greater magnitude of improvement in pts treated with SEC 300 mg than 150 mg.

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THU0312

RISK OF INFECTION IN PATIENTS WITH PSORIASIS/ PSORIATIC ARTHRITIS: A POPULATION-BASED STUDY IN THE PROVINCE OF BRITISH COLUMBIA

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Background: Psoriasis (PsO) is a chronic autoimmune disease of the skin with a third of patients (pts) also developing inflammatory arthritis (PsA), which can lead to joint destruction. Research suggests that pts with PsA have an increased risk of complications (e.g. cardiovascular disease). There are limited data on the risk of infections among pts with PsO/PsA.

Objectives: To assess the risk of mild and severe infections in pts with newly diagnosed PsO/PsA in a general population.

Methods: Using administrative health data from British Columbia (Canada) we developed an incident cohort of pts diagnosed with PsO/PsA between 1996 and 2013, with equal control pts matched on sex, age and calendar year. PsO/PsA cases were determined by: a) one International Classification of Diseases code (696.X) for PsO/PsA assessed by a rheumatologist or dermatologist; b) ≥2 diagnostic codes for PsO/PsA, ≥2 months apart in a 2 year period assessed by a non-rheumatologist or dermatologist; c) ≥1 hospitalisation with a diagnostic code for

PsO/PsA. Individuals with a history of HIV or tuberculosis were excluded. Outcomes were mild infections (requiring a physician visit and antibiotics) or serious infections (requiring hospitalisation). Adjusted risks of these infections were estimated using generalised estimating equation extensions of multivariate Poisson regression models.

Results: We identified 84 616 newly diagnosed pts with PsO/PsA (51.6% female; mean age 49.5 years [SD: 18.2]) who were matched with an equal non-PsO/PsA cohort. Pts with PsO/PsA had a higher risk of developing mild infections during follow-up, including HIV (2.6-fold) and mycosis (2-fold), compared with the general population. PsO/PsA also increased the risk of severe infections including *Chlamydia* (1.7-fold) and viral diseases with exanthema (2.6-fold) (table 1).

P-Y=patient years

Conclusions: This large epidemiological study demonstrates that pts with PsO/PsA are at significantly higher risk of acquiring infections. The role of therapy for PsO/PsA on the risk of these infections needs to be evaluated.

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THU0313

IXEKIZUMAB IMPROVES NAIL AND SKIN LESIONS THROUGH 52 WEEKS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO TUMOUR NECROSIS FACTOR INHIBITORS

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Background: Ixekizumab (IXE) is a high-affinity monoclonal antibody selectively targeting interleukin-17A. Compared to placebo (PBO), IXE resulted in significantly greater reduction and clearance of fingernail and skin lesions at Wk 24 in patients (pts) with active psoriatic arthritis (PsA) and inadequate response (IR) to tumour necrosis factor inhibitors (TNF-i).¹

Objectives: This analysis examined the persistence of effect at 1 year.

Methods: In this Phase 3, double-blind trial (SPIRIT-P2; NCT02349295), pts with active PsA who were TNF-i-IR were randomised to PBO or 80 mg IXE SC every 2 or 4 Wks (IXEQ2W, IXEQ4W), after a 160 mg starting dose.² At Wk 16, pts with IR to treatment (ERB supplement defined) received rescue therapy and pts on PBO

Abstract THU0312 – Table 1. Incidence Rate (IR) and Rate Ratio (RR) of Mild and Severe Infections Among PsO/PsA Pts Compared With the General Population

Outcomes	PsO/PsA cohort		Mild infections Non-PsO/PsA cohort		RR (95% CI)	Severe infections PsO/PsA cohort		Non-PsO/PsA cohort		RR (95% CI)
	n	IR (per 100K P-Y)	n	IR (per 100K P-Y)		n	IR (per 100K P-Y)	n	IR (per 100K P-Y)	
Viral diseases with exanthema	5612	912.7	3735	611.3	1.49 (1.43–1.56)	47	7.3	18	2.9	2.56 (1.49–4.40)
HIV-related infections	119	18.6	41	6.5	2.63 (1.91–3.63)	–	–	–	–	–
Intestinal infections	3659	587	2420	392.5	1.50 (1.42–1.57)	835	130.6	508	81	1.61 (1.44–1.80)
Mycoses	5318	867.9	2520	409.3	2.12 (2.02–2.22)	–	–	–	–	–
Poliomyelitis	78	12.2	48	7.6	1.59 (1.11–2.28)	–	–	–	–	–
Syphilis venereal	514	80.4	391	62.4	1.29 (1.13–1.47)	–	–	–	–	–
Tuberculosis	340	53.1	212	33.8	1.52 (1.29–1.79)	–	–	–	–	–
<i>Chlamydia</i>	3580	575.8	2140	346.8	1.66 (1.57–1.75)	113	17.6	67	10.7	1.65 (1.22–2.23)
Zoonotic	73	11.4	48	7.6	1.49 (1.03–2.14)	–	–	–	–	–
Pneumonia	9622	1613.1	6306	1053.4	1.53 (1.48–1.58)	1685	264.8	1236	198	1.34 (1.24–1.44)
Intracranial abscess	37	5.8	18	2.9	2.01 (1.15–3.53)	–	–	–	–	–
Rickettsioses	140	21.8	97	15.5	1.41 (1.09–1.83)	–	–	–	–	–
Helminthiasis	110	17.2	77	12.3	1.40 (1.05–1.87)	–	–	–	–	–

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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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)

	PBO (n=106)	IXE Q4W (n=107)	SPIRIT-1 ¹		PBO (n=118)	IXE Q4W (n=122)	SPIRIT-2 ²	
			IXE (95% CI) P Value ³	Q2W (95% CI) P Value ³			IXE (95% CI) P Value ³	Q2W (95% CI) P Value ³
MDA ⁴ , n (%)								
Week 24	16 (15.1)	32 (29.9)	14.8 (3.8, 25.8) 0.010	42 (40.6) (14.0, 37.4) 0.001	4 (3.4)	34 (27.9)	24.5 (15.9, 33.1) 0.001	20.2 (12.0, 28.4) 0.001
Week 52	NA	42 (39.3)	NA	38 (36.9)	NA	42 (34.4)	NA	29 (23.6)
MDA VLDA ⁴ , n (%)								
Week 24	1 (0.9)	11 (10.3)	9.3 (3.3, 15.4) 0.019	12 (11.7) (4.2, 17.2) 0.013	1 (0.8)	15 (12.3)	11.4 (5.4, 17.5) 0.006	4 (3.3) (1.1, 5.9) NA
Week 52	NA	15 (14.0)	NA	16 (15.5)	NA	15 (12.3)	NA	8 (6.5)
DAPSA LDA ⁴ , n (%)								
Week 24	19 (17.9)	34 (31.6)	13.9 (2.4, 25.3) 0.019	35 (34.0) (4.4, 27.8) 0.001	13 (11.1)	31 (25.4)	14.4 (4.8, 24.0) 0.003	34 (27.6) (6.9, 26.3) 0.001
Week 52	NA	33 (30.6)	NA	30 (29.1)	NA	42 (34.4)	NA	32 (26.0)
DAPSA Remission ⁴ , n (%)								
Week 24	5 (4.7)	17 (15.9)	11.2 (3.2, 19.2) 0.013	25 (24.3) (10.3, 28.8) 0.001	1 (0.8)	18 (14.8)	13.9 (7.4, 20.4) 0.003	9 (7.3) (1.6, 11.4) 0.039
Week 52	NA	24 (22.4)	NA	30 (29.1)	NA	23 (18.9)	NA	14 (11.4)
PASDAS LDA ⁴ , n (%)								
Week 24	20 (18.9)	45 (42.1)	23.2 (11.3, 35.1) 0.001	52 (50.6) (19.4, 43.8) 0.001	8 (6.6)	48 (39.3)	32.6 (22.8, 42.3) 0.001	43 (35.0) (18.6, 37.8) 0.001
Week 52	NA	46 (43.0)	NA	52 (50.6)	NA	55 (45.1)	NA	38 (30.9)
PASDAS VLDA ⁴ , n (%)								
Week 24	2 (1.9)	12 (11.2)	9.3 (2.8, 15.8) 0.016	21 (20.4) (10.3, 26.7) 0.001	0 (0.0)	16 (13.1)	13.1 (7.1, 19.1) 0.001	9 (7.3) (2.7, 11.9) 0.003
Week 52	NA	19 (17.8)	NA	27 (26.3)	NA	21 (17.3)	NA	14 (11.4)

Abbreviations: CI, confidence interval; DAPSA, Disease Activity in Psoriatic Arthritis; DIF, difference; ITT, intent-to-treat; IXE Q2W, ixekizumab 80mg every 2 weeks; IXE Q4W, 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 adalimumab active comparator arm in SPIRIT-1 total trial. ²IXE was controlled using the sample size method, without continuity correction (normal approximation to binomial distribution). ³P-values 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 (see table 1). See table 1 for joint count (JC), Psoriasis Area and Severity Index (PASI), and tender and swollen joint counts (TJC and SJC). Patient's assessment of pain (visual analog scale [VAS]) (0=not at all, 10=worst imaginable) was used for DAPSA VLDA. Health-related quality of life (SF-36) was used for PASDAS VLDA. PASDAS VLDA was defined as PASDAS VLDA 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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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.