Abstract SAT0341 – Table 1. Efficacy and safety results of an interim analysis of the extension period population of SPIRIT-P2.

	IXE Q4W (N=111)	IXE Q2W (N=107)	PBO/IXE Q4W (N=46)	PBO/IXE Q2W (N=46)
Week 52 Responder Rate, n/N (%), NRI				
ACR 20	75/111 (68)	63/107 (59)	28/46 (61)	23/46 (50)
ACR 50	51/111 (46)	41/107 (38)	20/46 (44)	16/46 (35)
ACR 70	32/111 (29)	22/107 (21)	11/46 (24)	7/46 (15)
MDA	42/111 (38)	29/107 (27)	14/46 (30)	13/46 (28)
LEI (0)^a	32/61 (53)	30/73 (41)	13/24 (54)	12/29 (41)
LDI-B (0)^b	21/26 (81)	11/16 (69)	7/7 (100)	2/6 (33)
PASI75^c	41/62 (66)	37/57 (65)	19/25 (76)	15/31 (48)
PASI90^c	34/62 (55)	27/57 (47)	18/25 (72)	14/31 (45)
NAPSI (0)^d	41/81 (51)	24/67 (36)	10/29 (34)	9/25 (36)
Week 52 Mean (SD) Change from Baseline, mBOCF				
HAQ-DI	-0.4 (0.5)	-0.4 (0.5)	-0.4 (0.4)	-0.2 (0.5)
DAS 28-CRP	-2.2 (1.5)	-1.9 (1.3)	-2.0 (1.3)	-1.6 (1.3)
Safety Overview (Weeks 24-156), n (%)				
TEAE	79 (71)	68 (64)	32 (70)	27 (59)
SAE	6 (5)	4 (4)	2 (4)	3 (7)
Discontinued due to AE	2 (2)	8 (8)	0 (0)	2 (4)

For efficacy analyses, baseline was defined as assessment recorded on or prior to Week 0. For analyses of TEAEs, baseline was defined as AEs that started prior to the study drug injection at Week 24. ^aAssessed only in patients with enthesitis and LEI >0 at baseline; ^bAssessed only in patients with dactylitis and LDI-B >0 at baseline; ^cAssessed only in patients with psoriatic lesions ≥3% of BSA at baseline; ^dAssessed only in patients with fingernail psoriasis at baseline. **Abbreviations:** ACR20/50/70=20/50/70% improvement in the ACR; ACR=American College of Rheumatology; BSA=body surface area; DAS28-CRP=Disease Activity Score based on a 28 joint count with C-reactive protein; HAQ-DI=Health Assessment Questionnaire-Disability Index; LDI-B=Leeds Dactylitis Index-Basic; LEI=Leeds Enthesitis Index; mBOCF=modified baseline observation carried forward; MDA=minimal disease activity; NAPSI=Nail Psoriasis Severity Index; NRI=nonresponder imputation; PASI75/90=Psoriasis Area and Severity Index 75/90; SAE=serious adverse event; TEAE=treatment-emergent adverse event

Conclusions: IXE demonstrated sustained improvement in the signs and symptoms of PsA across treatment groups during the EP. The safety profile of IXE observed in the EP population was consistent with the safety profile of the intent-to-treat population in the DBTP of SPIRIT-P2.¹

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SAT0342 INFLAMMATORY BACK PAIN IN PSORIATIC ARTHRITIS IS SIGNIFICANTLY MORE RESPONSIVE TO CORTICOSTEROIDS COMPARED TO BACK PAIN IN ANKYLOSING SPONDYLITIS: A PROSPECTIVE, OPEN-LABELLED, CONTROLLED PILOT STUDY

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Background: Inflammatory spinal disease is one of three inflammatory musculoskeletal manifestations which frequently occur in PsA. There is very limited data about the axial involvement in PsA, especially as regards treatment, with

treatment guidelines based largely on data from AS trials. The efficacy of corticosteroids in PsA patients with inflammatory back pain has not been studied to date. **Objectives:** In this controlled trial, we aimed to investigate the comparative performance of corticosteroids for active axial-PsA (AxPsA) versus those with active AS.

Methods: PsA patients (fulfilling CASPAR criteria), and AS as per the 1984 Modified New York Criteria, were suitable for inclusion. Among them, patients with active AxPsA and active AS ((naïve to biologic therapies) were recruited. The active disease was defined as patients with inflammatory back pain, with spinal pain score of ≥4 and BASDAI score ≥4 despite taking NSAIDs. Furthermore, only those AxPsA and AS patients with an MRI proven sacroiliac joint bone marrow oedema (MRI of sacroiliac joints performed within the 6 months prior to recruitment) were considered for inclusion. Hence, all recruited patients with AxPsA and AS had not only clinically active disease, but also had bone marrow oedema on MRI of sacroiliac joints. Moreover, we recruited a control group of non-inflammatory lower back pain. All patients received a single, intra-muscular dose of depot corticosteroid injection (Triamcinolone Acetonide 80 mg) at baseline. The intra-muscular corticosteroid option was used to overcome any drug compliance issues. Clinical outcome assessments were made at following time points: baseline, week-2, and week-4. The primary efficacy end point was the mean change in Ankylosing Spondylitis Disease Activity Score (ASDAS) at week-2. Key secondary outcome were the mean change of BASDAI, BASFI and ASQoL at week-2 and week-4.

Results: In total, 40 patients were recruited – AxPsA=15, AS=15, control=10. At week-2 following corticosteroid treatment, patients with AxPsA had significantly higher improvements in the mean ASDAS compared to patients with AS (1.43 ±0.39 vs. 1.03±0.30, p=0.004), and the same was the case when compared to controls (p<0.001, table-2, figure-1). At week-4, AxPsA patients also showed significantly higher improvements in the mean ASDAS compared to both AS patients (1.09±0.32 vs. 0.77±0.27, p=0.007) and controls (p<0.001). Similarly, the mean BASDAI, VAS spinal pain score, ASQoL and BASFI improved significantly among AxPsA patients compared to AS patients and controls at week-2, with this trend also largely maintained at week-4

Conclusions: Axial inflammation in PsA potentially responds significantly better to corticosteroids than in patients with AS. This furthers the argument and adds to the growing evidence that AxPsA and AS are distinct entities. Future studies should further investigate the use of corticosteroids and of sDMARD usage among patients with active IBP in PsA.

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SAT0343 CARDIOVASCULAR DISEASE RISK IN CLINICAL SUBTYPES OF PSORIATIC ARTHRITIS

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Background: Patients with psoriatic arthritis (PsA) have been shown to be at increased risk of developing cardiovascular disease (CVD), with one recent meta-analysis demonstrating an increased CVD risk of 43% compared to the general population. However PsA is a heterogeneous disease consisting of five different clinical subtypes. It is not known whether the risk of CVD varies between different PsA subtypes.

Objectives: To determine whether particular subtypes of PsA are associated with an increased risk of cardiovascular disease.

Methods: 114 patients with PsA attending the University Hospital of Wales were asked to complete a questionnaire about their cardiovascular risk factors. Anthropometric and biochemical measurements, including blood pressure, body mass index (BMI), C-reactive protein (CRP) and cholesterol, were also performed. Patients were grouped into one of the five PsA subtypes as described by Moll and Wright. The QRISK2 algorithm was used to determine the 10 year risk of developing CVD for each patient. Multivariate analyses using linear and logistic regression with QRISK2 score and QRISK2 score >10% as dependent variables were conducted and adjusted for known cardiovascular risk factors.

Results: Symmetrical polyarthritis was the most common subtype, no patients had arthritis mutilans. There were no statistically significant differences between the subtypes with regards to age, gender, BMI, blood pressure, smoking status, cholesterol or CRP. Statistically significant differences were found between the subtypes using Chi-square (χ²) tests for QRISK2 score >10% (p=0.031) as well as the presence of existing cardiovascular disease, diabetes mellitus and cholesterol lowering treatment (p=0.021, 0.021 and 0.037 respectively). The table 1 below lists the number of patients by subtype and these variables.

	Asymmetrical/ oligo-articular	Distal interphalangeal (DIP) predominant	Spinal predominant	Symmetrical polyarthritis
n (out of 100)	24	9	13	68
Age (mean±SD)	51.3±15.0	61.4±7.8	58.8±13.7	50.7±15.2
Male (n,%)	14 (58.3)	5 (55.6)	6 (46.2)	32 (47.1)
Presence of cardiovascular disease (n,%)*	1 (4.2)	0 (0)	3 (23.1)	1 (1.5)
History of diabetes mellitus (n,%)*	6 (25.0)	2 (22.2)	3 (23.1)	3 (4.4)
On cholesterol- lowering treatment (n, %)*	4 (16.7)	1 (11.1)	6 (46.2)	9 (13.2)
QRISK2 risk score (mean±SD)	12±12.3	15.1±8.5	18.8±13.9	11.1±13.3
Those with QRISK2 risk score>10% (n,%)*	9 (37.5)	7 (77.8)	8 (61.5)	23 (33.8)

*denotes p<0.05

Conclusions: PsA patients with symmetrical polyarthritis appear to have the lowest risk of developing CVD. This subtype also had a significantly lower proportion of patients with coexisting diabetes mellitus. Patients with the distal interphalangeal (DIP) subtype are more likely to have existing CVD and be on cholesterol-lowering medications. Patients with the DIP and spinal predominant subtypes of PsA are also more likely to have a QRISK2 score of greater than 10% compared to the other PsA subtypes, suggesting they are more likely to develop CVD and may consequently need closer monitoring and management of CVD risk factors.

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SAT0344 THE EFFECT OF GUSELKUMAB ON ENTHESITIS: 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) w/meaningful improvements in enthesitis.

Objectives: To evaluate the effect of GUS on enthesitis in a subset of pts w/ enthesitis at baseline (BL) from 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 or placebo (PBO) at weeks (wks) 0, 4, then every 8 wks (q8w) during a 24-wk double-blind treatment period. At wk16, pts w/<5% improvement in swollen and tender joint counts early escaped (EE) to open-label ustekinumab. At wk24, the PBO group crossed over to receive GUS at wks 24, 28 then q8w (PBO→GUS) and the GUS group continued receiving GUS (GUS→GUS) through wk44. Enthesitis was assessed using the Leeds enthesitis index (LEI). Enthesitis scores during the 24-wk double-blind treatment was analysed using LOCF imputation for missing data and EE. Enthesitis after wk24 was analysed using observed data.

Results: Of 149 total pts w/active PsA, 107 (72%) presented w/enthesitis at BL (PBO n=31, mean [SD] LEI=2.6 [1.48], median [range]=2.0;¹ GUS n=76, mean (SD) LEI=2.7 [1.54], median [range]=2.0¹, ⁶) and 85 continued at Wk24 (PBO→GUS n=18; GUS→GUS n=67). Except for higher tender/swollen joint counts and CRP, BL characteristics of the enthesitis subset was similar to the overall population. GUS significantly reduced the LEI by wk8 (mean [SD] change from baseline, PBO: -0.4 [1.59]; GUS: -1.2 [1.65]; p=0.037), and through wk24

(mean [SD] change from baseline, PBO: -0.7 [1.53]; GUS: -1.5 [1.81]; p=0.045). GUS also significantly increased the% of pts w/enthesitis resolution (figure 1). After wk24, the PBO→GUS group achieved rapid, sustained resolution (wk56: mean[SD] change from BL=-2.1 [1.65]; 62.5% of pts w/resolution), similar to GUS→GUS group (wk56: mean[SD] change from BL=-1.9 [1.59], 70.8% of pts w/resolution). Improvement in enthesitis was observed at each enthesitis site assessed, and was greater in ACR20 (Table) responders vs non-responders in GUS-treated patients and was correlated w/improvement in tender (R=0.37, p=0.001) and swollen (R=0.27, p=0.020) joint counts, physician's (R=0.47, p<0.0001) and patient's global assessment of disease activity (R=0.32, p=0.005), and SF36 PCS (R=0.27, p=0.02) and MCS (R=0.35, p=0.002).

Abstract SAT0344 – Table 1. Change in LEI in ACR20/50 and PASI75 Responders and Non-responders

	Mean (SD) change from BL in LEI at Wk24		
	Non-responders	Responders	p-value
ACR 20	-0.93 (2.054), n=28	-2.06 (1.660), n=47	0.002
ACR 50	-1.55 (2.190), n=49	-1.81 (1.132), n=26	0.057
PASI 75	-1.25 (1.138), n=12	-1.71 (1.995), n=63	0.524

Abstract SAT0344 – Figure 1. Proportion of Patients with Enthesitis Resolution over Time

Conclusions: GUS treatment produces rapid and sustained improvement of enthesitis in pts w/active PsA, which correlates w/improvement in joint symptoms and patient-reported outcomes.

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