Figure 1. ACR20, ACR50, and ACR70 Response Rates (IXEQ4W treatment) at Each Post-Baseline Visit by Concomitant cDMARD Use. Abbreviations: ACR, American College of Rheumatology; AE, adverse event; cDMARD, conventional synthetic disease-modifying antirheumatic drugs; IXEQ4W, ixekizumab 80 mg every 4 weeks; mNR, modified non-responder imputation.

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SAT0411

EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO TNF INHIBITORS: THREE YEAR RESULTS FROM A PHASE 3 STUDY (SPIRIT-P2)

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Background: Ixekizumab (IXE) is a high affinity monoclonal antibody that selectively targets interleukin-17A. In the SPIRIT-P2 study, IXE every 4 (Q4W) or 2 (Q2W) weeks was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in patients (pts) with prior inadequate response or intolerance to 1 or 2 tumor necrosis factor inhibitors (TNFi).

Objectives: To determine efficacy and safety of IXE treatment up to 3 years in pts with PsA.

Methods: In SPIRIT-P2 (NCT02349295), 310 pts entered the extension period where pts maintained their original ixekizumab dose, and placebo pts received IXEQ4W or IXEQ2W (1:1). Pts failing to demonstrate $\geq 20\%$ improvement in both tender and swollen joint counts at Week 32, or any subsequent visit, were discontinued (mandatory discontinuation criteria). Efficacy outcomes were ACR20/50/70 response, Psoriasis Area and Severity Index (PASI) 75/90/100 response, Leeds Enthesitis Index (LEI), Leeds Dactylitis Index-Basic (LDI-B), Minimal Disease Activity (MDA), and Disease Activity in Psoriatic Arthritis (DAPSA). Ad-hoc efficacy data are presented for intent-to-treat (ITT) pts initially randomized to IXE at Week 0. Observed and modified non-responder imputation (mNRi); missing data treated as non-response for pts discontinued due to lack of efficacy or adverse events (AEs) was applied to categorical measures. Observed and modified baseline observation carried forward (mBOCF) was applied to continuous efficacy measures. Safety was analysed in pts exposed to at least one dose of IXE.

Results: Of the 245 pts initially randomized to IXE at Week 0 (ITT), 64 (26.1%) pts discontinued due to lack of efficacy and 22 (9.0%) pts due to mandatory discontinuation criteria. Efficacy results are summarized below (Figure 1). Pts in SPIRIT-P2 who received IXEQ4W and IXEQ2W for 156 weeks reported sustained improvement in ACR responses and manifestations of PsA, including enthesitis, dactylitis, and skin outcomes. Treat-to-target measures such as MDA and DAPSA (Low Disease Activity or Remission) were achieved by 30.8% and 47.7% of pts, respectively on IXEQ4W, and by 29.2% and 40.7% of pts, respectively on IXEQ2W. Incidence rates (IR) of treatment-emergent adverse events (TEAEs) are provided below (Figure 2). Most TEAEs were mild or moderate in severity, and 38 out of 337 (5.9%) pts (safety population) discontinued due to AEs. The most common TEAEs were infections (IR=33.1) and injection site reactions (IR=5.4). Three deaths were reported in the study.

Figure 1. Efficacy Outcome Measures at Week 156 (Intent-to-treat Population). ACR=American College of Rheumatology; IXE=ixekizumab; LEI=Leeds Enthesitis Index; LDI-B=Leeds Dactylitis Index-Basic; mNRi=modified non-responder imputation; PASI=Psoriasis Area and Severity Index; Q2W=every two weeks; Q4W=every four weeks.

Figure 2. Safety Outcome Measures (Weeks 0-156). Safety was analysed in patients exposed to at least one dose of ixekizumab. During the double-blind treatment period (Weeks 0-24), one patient reported serious adverse events of anal fistula and anal abscess, which were considered by the sponsor to be IBD; however, an independent adjudication committee of external experts reviewed the case and determined the events to be "Not IBD."

Conclusion: In pts treated with IXE who had prior inadequate response or intolerance to 1 or 2 TNFi, improvements in the signs and symptoms of PsA persisted up to 3 years. No unexpected safety signals were observed, and the safety profile was consistent with previous studies of IXE.

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SAT0412

ACCURACY OF AN INSTRUMENT FOR SCREENING PSORIATIC ARTHRITIS AMONG PSORIATIC PATIENTS: RESULTS FROM THE MULTICENTRE ITALIAN STUDY HERACLES (SCREENING STRATEGIES FOR RHEUMATOLOGICAL REFERRAL OF PSORIATIC SUBJECTS AIMED TO DISCLOSE PSORIATIC ARTHRITIS)

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Background: Identifying psoriatic arthritis (PsA) among people with psoriasis is often challenging due to low specificity of symptoms at early PsA stage and/or delayed referral to the rheumatologist. Screening instruments -assisting the dermatologist to decide when rheumatological assessment is beneficial- have potential to reduce the diagnostic delay.

Objectives: To evaluate the accuracy of a dermatologist-filled-out questionnaire designed for screening PsA among psoriatic patients under dermatology care.

Methods: HERACLES is a multicentre, cross-sectional study running at 9 Italian dermatology and rheumatology tertiary centres. All participants were under dermatology care for skin psoriasis. Previous diagnosis of PsA precluded eligibility. Dermatologists at each site assessed consecutive psoriatic subjects, filled in the specifically-designed HERACLES questionnaire (HQ, Figure 1) and finally referred the participants to rheumatologists for clinical evaluation. All participants filled in the ToPAS, PASE, PEST and EARP questionnaires. Rheumatologists assessed the participants regardless of the questionnaires' scores. The gold standard applied to assess the instruments' accuracy was the diagnosis of PsA as established by the rheumatologists. ROC curve analysis evaluated the performance of the scores associated with the clinical criteria listed in the HQ, estimating the sensitivity and specificity of different cut-off levels. Further exploratory ROC curve analysis compared HQ performance to that of the other four questionnaires tested.

Final set of clinical referral criteria: model of a form							
CENTRE NAME							
PATIENT'S DETAILS	Surname Name	Date of birth Age Sex		Date of collection			
	Psoriasis form	Age at psoriasis onset		Nail psoriasis YES NO			
	Familial history for psoriasis	Familial history for rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis		Height Weight			
					Current PASI score		
	Current dermatological therapies		Previous dermatological therapies				
The patient complains of musculo-skeletal discomfort				YES		NO	
ITEM		DETAILS		YES	NO	ITEM SCORE	
1	The patient complains of arthralgias	Pain in one or more articular sites, continuous for at least 6 weeks, not due to trauma. The complain may be spontaneous or elicited		1	0		
2	The patient complains of spinal pain	Mostly at night, continuous, improves with exercise, insidious onset, for at least 8 weeks		1	0		
3	The patient reports history of heel discomfort	Entheses are the sites of insertion of tendons, ligaments and muscles on bones. The most important sites are the plantar fascia and Achilles' tendon at the heels		1	0		
4	The dermatologist sees joint swelling	Articular swelling, usually associated with pain, warmth and redness, not due to trauma		1	0		
5	The patient reports history suggestive of dactylitis OR The dermatologist sees digital swelling	Finger(s) or toe(s) are swollen, appearing as "sausages". There may be redness and pain, the onset may be insidious or acute. Rule out trauma. Comparison of the involved finger/toe with the other side is usually very helpful.		2	0		
6	The dermatologist sees joint deformity	Alteration of joints profiles, telescoping fingers/toes		1	0		
7	The dermatologist sees the patient limping	The patient comes to visit limping. Rule out trauma. Investigate elective surgery		1	0		
TOTAL SCORE (0-8)							
If total score is 2 or more, consider referral to rheumatologist							

Figure 1.

Results: Out of 759 subjects enrolled, 524 (69%) attended rheumatology assessment. Rheumatologists diagnosed PsA in 73/524 patients (13.9%, Figure 2). Mean age was 53 (SD 16) years and 46% were female. Mean psoriasis duration was 20 (SD 19) years. The area under the ROC curve of HQ was 0.775. The HQ score cut-off value of 2 yielded a sensitivity of 92% and a specificity of 47%; a cut-off value of 3 yielded a sensitivity of 66% and a specificity of 75%. The comparison between the ROC curve of the HQ and those of the other four questionnaires evaluated did not show any significant difference (p=0.523 versus TOPAS; p=0.201 versus PASE; p=0.345 versus PEST and p=0.240 versus EARP).

Flow Chart, HERACLES study

Figure 2.

Conclusion: The HERACLES questionnaire, a tool designed for dermatologists, showed good sensitivity and specificity in identifying PsA cases among subjects with cutaneous psoriasis.

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SAT0413 DACTYLITIS IS ASSOCIATED WITH DISEASE SEVERITY AND ULTRASOUND DEFINED EROSIIVE DAMAGE IN VERY EARLY, DMARD NAÏVE PSORIATIC ARTHRITIS

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Background: Dactylitis is a hallmark feature of Psoriatic arthritis (PsA) and Spondyloarthritis (SpA) defined as a uniform swelling of a digit ("sausage digit"). Dactylitis is associated with radiographic damage in chronic PsA. However, there are a paucity of data on the significance of dactylitis and its potential impact in disease burden in early PsA.

Objectives: To characterize a very early DMARD naïve PsA cohort based on clinical presence or absence of dactylitis at disease onset.

Methods: PsA subjects fulfilling the CASPAR classification criteria, were recruited into a prospective observational cohort, the Leeds Spondyloarthropathy Register for Research and Observation (SpARRO) after providing informed written consent. Clinical data including tender (TJC) and swollen joint counts (SJC) were independently assessed. Dactylitis was recorded per digit (finger or toe) as tender (hot) or non-tender (cold). Differences in baseline characteristics were evaluated using percentages to describe categorical variables and means and standard deviations for continuous variables, p value of the mean/proportion difference was calculated. Ultrasound (US) examination was conducted by trained ultra-sonographers blinded to clinical details. Bone erosions were defined on US if intra-articular discontinuity was present in two perpendicular planes at any of 46 joints: wrists, MCP1-5, PIP2-5, DIP2-5, MTP1-5, knees, ankles, subtalar, talonavicular.

Results: A total of 177 PsA patients were recruited. Dactylitis was seen in nearly half the cohort [n=83 (47%)]. Patients with dactylitis had significantly more early morning stiffness, higher TJC and SJC, compared with non-dactylitis (Table 1). A total of 211 digits with dactylitis were recorded in 83 patients. Dactylitis of multiple digits was seen in 47/83 (57%) patients whilst a single dactylitic digit occurred in 36/83 (43%). Foot involvement was more prevalent (141/211, 67%) than hands (70/211, 33%). "Hot" or tender dactylitis was more frequently detected (153/211,