ACR20/50/70 at Weeks 12 and 24, static Investigator Global Assessment of psoriasis (sIGA) of 0 or 1 (clear or almost clear) and at least a 2-point improvement from baseline, and PASI75 at Weeks 16 and 24 or experiencing selected clinically relevant safety events through week 24.

Results: Analyses were conducted using data from 1694 subjects (for pharmacokinetics) and 1916 subjects (for exposure-response analyses). UPA model-estimated plasma exposures in subjects with PsA who received 15mg and 30mg QD doses were comparable to previously estimated exposures in subjects with RA. Body weight and methotrexate use had no clinically relevant effects on UPA exposures. There was a statistically significant relationship between UPA Cavg and the percentage of subjects who achieved Week 12 ACR50/70, Week 16 sIGA 0/1, and Week 24 sIGA 0/1 (Figure 1). No statistically significant exposure-response relationship was observed for Week 12 ACR20, Week 16 PASI75, or Week 24 ACR20/50/70 or PASI75, indicating that the 15mg QD exposures are approximately at the plateau of response for these endpoints. No statistically significant relationships were observed between upadacitinib Cavg and the percentage of subjects experiencing pneumonia, herpes zoster, hemoglobin < 8 g/dL, Grade ≥3 lymphopenia, Grade ≥3 neutropenia. There was a shallow but statistically significant exposure-response relationships with the occurrence of serious infections and decrease in hemoglobin from baseline (>2 g/dL and >2 g/dL in combination with hemoglobin < lower limit for normal).

Figure 1. Observed and Model Predicted Efficacy Responses at Week 12 (for ACR50/70) or at Weeks 16 and Week 24 (for sIGA 0/1) Versus Upadacitinib Plasma Exposures

Conclusion: Exposure-response analyses demonstrated that plasma exposures associated with UPA 15mg QD achieves robust efficacy in subjects with PsA with limited effects on the evaluated safety endpoints. UPA plasma exposures associated with UPA 15 and 30mg QD are predicted to provide similar ACR responses by week 24 while a small additional efficacy benefit with UPA 30mg is predicted for the achievement sIGA 0/1.

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POS1055

HIGH SATISFACTION WITH USTEKINUMAB TREATMENT IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS – FINAL RESULTS OF THE NON-INTERVENTIONAL STUDY SUSTAIN DEMONSTRATE EARLY AND LONG-TERM TREATMENT RESPONSE AND HIGH TOLERABILITY

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Background: From February 2015 to April 2020, patients with active psoriatic arthritis under treatment with ustekinumab in routine clinical care in Germany were included into the prospective, multi-center non-interventional study SUSTAIN.

Objectives: Here, we present final data from SUSTAIN including final week 160 on long term efficacy and safety of ustekinumab treatment, quality of life and further patient reported outcomes.

Methods: In SUSTAIN, 337 patients were treated with ustekinumab according to routine clinical care at 75 centers for 160 weeks with documentation intervals at week 0 and 4 and then every 12 weeks. The collected data included demographics, number of swollen and tender joints, tender entheses, amount of skin symptoms (BSA and PASI), patient reported outcome concerning disease activity and pain, Health Assessment Questionnaire (HAQ), quality of life (SF-12), sleep quality (VAS), satisfaction with therapy of patient and physician, safety (adverse events [AE]/serious adverse events [SAE]), pharmacoeconomic aspects, number of patients with „Minimal Disease Activity“ (MDA) and number of patients with MDA at week 28 and 52. For this analysis, final data of all 337 patients of all documented visits were analyzed.

Results: The visit at week 4 was documented for 31 patients, at week 28 for 282, at week 52 for 216, and at week 160 for 129 of the 337 patients. At baseline, the patients had a mean age of 53.6 years (22-85) and 192 (57%) were female. The patients' mean BMI was 29.6 kg/m² (18.6-52). 54.3 % of the patients had at least one TNF inhibitor as prior medication. 54.1 % of the patients used MTX as concomitant medication. At time of inclusion, 73.3% of the patients showed arthritis at small and 52.2% at large joints. 16.9% showed spinal involvement and 13.1% enthesitis. In the course of the treatment, the number of tender joints improved from a mean of 10.0 (CI 95% 8.6/11.3) at baseline to 4.1 (3.2/4.9) at week 28, 3.6 (2.7/4.6) at week 52 and 1.0 (0.6/1.4) at week 160. Number of swollen joints improved from 4.1 (3.4/4.9) at baseline to 1.8 (1.2/2.3) at week 28, to 1.3 (0.8/1.8) at week 52 and to 0.4 (0.2/0.6) at week 160. BSA declined from a mean of 15.6% (range from 0 to 80.0%) at baseline to 5.2% (0 to 60%) at week 28, to 3.0% (0 to 45.0%) at week 52 and to 1.7 (0 to 35%) at week 160. PASI declined from a mean of 7.3 (range from 0 to 43.0) at baseline to 1.7 (0 to 24.8) at week 28, to 1.3 (0 to 28.5) at week 52 and to 0.5 (0 to 3.2) at week 160. Efficacy of the therapy with ustekinumab was assessed as „very good“ or „good“ by 85.3% of the treating physicians at week 52 and by 94.1% at week 160. The patients assessed the efficacy as „very good“ or „good“ by 82.8% at week 52 and by 89.8% at week 160. At the end of the study, 96 SAEs have been documented, of which only 16 were related to ustekinumab. All in all, safety of therapy with ustekinumab was assessed as „very good“ or „good“ by 99% of the treating physicians after 52 weeks and by 99.2 % after 160 weeks. The patients assessed the safety as „very good“ or „good“ by 97.5% at week 52 and by 100% at week 160.

Conclusion: The non-interventional study SUSTAIN showed relevant disease improvements and good safety with an outstanding high therapy satisfaction in patients with active psoriatic arthritis treated with ustekinumab. Treatment effect was observed as early as after 4 weeks. The treatment effects and satisfaction sustained up end of documentation at week 160 in daily practice life.

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POS1056

COMPARATIVE EFFICACY OF TNF INHIBITORS VERSUS OTHER CYTOKINE INHIBITOR bDMARDs ON PSORIATIC ARTHRITIS IMPACT OF DISEASE (PsAID) SCORE AND DOMAINS

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Background: Psoriatic arthritis (PsA) has many consequences, reflecting musculoskeletal and skin inflammation, with the potential to adversely affect overall quality of life. Patient reported outcome measures (PROM) assess a holistic range of aspects of quality of life, including physical and mental components, and provide broad detailed information of the impact of disease. Biologic DMARDs (bDMARDs) targeting TNF have been used to treat PsA for over 10 years whereas inhibitors of IL-17, IL-12/23 and Janus kinases (JAK) have only been available more recently. They all target differing cytokines, including JAK inhibitors which inhibit IL-12 and IL-23 signaling but not TNF signaling. Their relative impact on PROMs is unknown.

Objectives: To assess, in routine care, the relative impact in PsA of TNF inhibitors (TNFi) versus non-TNFi bDMARDs, targeting IL-17, IL-12/23 and JAK, on PROMs.

Methods: We performed a cross section analysis of PsA patients with established disease treated with bDMARDs and JAKi, under routine care at St George's University Hospital, London, UK. Patients completed the 12-item psoriatic arthritis impact of disease (PsAID) tool. The total PsAID score was calculated using the on-line EULAR toolkit (see reference). The PsAID total and individual domain scores were compared between TNFi and non-TNFi groups using the

Mann Whitney U test. A total PsAID score below 4 out of 10 is considered a 'patient-acceptable state'.

Results: A total 95 patients (female n= 53, 56%) completed the PSAID; TNFi n=72 (female 50%, adalimumab n=41, Etanercept n= 24, Golimumab n=4, Infliximab n =2, Certolizumab n=1) and non-TNFi n= 23 (female 74%, Secukinumab n=9, Ixekizumab n=1, Ustekinumab n=9, Tofacitinib n=4). The mean age was 53.6 (TNFi 53.5, non-TNFi 53.7) years, and duration of time on bDMARD treatment was TNFi 49.5 (range 1- 141) months, non-TNFi 25.3 (range 4 -59) months. The total and individual domain PSAID scores are shown in the Table 1. A 'patient acceptable state' total score <4 was recorded in TNFi 36/72 (50%) and non-TNFi 11/23 (48%). There was no significant difference between TNFi and non-TNFi groups in the mean total PSAID score, or proportion achieving a patient acceptable state. Patients on TNFi had lower (better outcome) mean scores for all 12 domains except skin, and the differences, versus non-TNFi treated patients, were significant for pain, functional capacity, discomfort and depression.

PSAID domain	TNFi	Non-TNFi	P value
Total score	3.31	4.64	N.S.
Pain	3.67	5.43	0.02
Fatigue	4.04	5.65	N.S.
Skin problems	3.11	2.78	N.S.
Work/leisure activities	3.56	4.78	N.S.
Functional capacity	3.29	5.04	0.02
Discomfort	3.88	5.65	0.02
Sleep disturbance	3.42	4.78	N.S.
Coping	3.01	4.09	N.S.
Anxiety, fear, uncertainty	2.64	4.17	N.S.
Embarrassment/shame	2.28	3.39	N.S.
Social participation	2.6	3.48	N.S.
Depression	2.11	3.91	0.03

Conclusion: In PsA, TNFi appear to have a greater impact over non-TNFi bDMARDs on some aspects of quality of life, including pain and functional capacity. TNFi and non-TNFi were no different with respect to patients' perspective on skin disease, embarrassment or shame, despite less good cutaneous responses in clinical trials from TNFi agents. Overall, the PsAID tool reveals an unmet burden on quality of life in PsA patients treated with all classes of bDMARDs and JAKi, as 50% fail to achieve a 'patient acceptable state'. This should prompt scrutiny of the high scoring domains and utilization of additional treatment modalities to achieve better holistic outcomes for PsA patients in routine care.

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POS1057

DISCONNECT BETWEEN TREATMENT SWITCHES AND DISEASE ACTIVITY STATE IN EARLY PSORIATIC ARTHRITIS

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Background: Receiving adequate treatment early in the disease course is one of the most important prognostic factors to achieve optimal disease outcome in most rheumatological conditions. Treat-to-target strategies and early step-up of treatment are important ingredients to accomplish this. While for Rheumatoid Arthritis this is common practice on accepted targets, for Psoriatic Arthritis (PsA) this is less outspoken practice. In PsA multiple domains must be taken into account and also there is a less established practice to use PsA specific targets, such as MDA, although this is associated with a better quality of life.[1,2] Whether this affects optimal disease outcome is not well described

Objectives: To describe treatment strategies in newly diagnosed PsA with at least one synovitis and, treatment switches over time in those that not achieved MDA.

Methods: For this study we used data from the DEPAR study between August 2013 and February 2019. The DEPAR study is a cohort that includes newly diagnosed PsA patients and follows them for up to 6 years. Patients are classified at baseline according to their prominent features: mono-, oligo-, polyarthritis, enthesitis, dactylitis or axial phenotype. For this study we used the data from the first 2 years for the patients with an articular phenotype. Methotrexate (MTX) and MTX plus another s-DMARD or GCs were addressed separately as they form the cornerstone of treatment in PsA. Next treatment was grouped in the usual drug classes: sDMARD (conventional), bDMARD and Glucocorticoids (GCs). Descriptive statistics were applied in STATA16 and Tableau 2020.3

Results: Out of 620 patients, 478 patients had at least one swollen joint at baseline and were included in this analysis. 349 (73%) had data at 1 year and 267

(56%) at 2 years. Average age was 50.3 years(sd 14.1), and 50% was female. Half of the patients had oligo-arthritis, 30% poly-arthritis and 20% mono-arthritis. At baseline, clinical characteristics were 3.8 swollen joints (sd 4.9), 5.5 tender joints (sd 6.2), 3.1 PASI points (sd 3.7, skin), 0.8 enthesal points (LEI; sd 1.2) and 0.1 dactylitis count (basic count of digits; sd 0.6). Treatment was initiated with Monotherapy MTX in 51% of the patients, while 25% did not start any DMARD, 10% started a combination of s-DMARDs, 9% a single s-DMARD, 3% a b-DMARD and 2% GCs. This differed for the different phenotypes as shown in Table 1.

Minimal Disease Activity (MDA) was achieved by 32% after 3 months increasing to 58% at 24 months. Treatment switches in the non-MDA mono-, oligo- and polyarthritis groups are shown in Figure 1. In the patients not in MDA treatment was not switch in: 70% of patients with mono-arthritis, 50-66% with oligo-arthritis and 50% poly-arthritis. Similar observations were found when using the DAS28(<=3.2) or DAPSA(<14), both including only articular disease activity (data not shown).

Conclusion: Achieving MDA is associated with a better quality of life, though it is not yet common practice to make treatment adjustments based on MDA. Of the newly diagnosed PsA patients not in MDA, more than half of the clinical evaluations did not result in a switch of medication.

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Figure 1. Medication change in patients not in MDA at each timepoint (dark bars = change and light bars = no change)

table 1 baseline medication

diagnosis	MTX mono	none	combi s-dmard	s-DMARDs	b-DMARDs	MTX+ GCs	GCs
monoarthritis	28%	58%	5%	6%	1%		2%
oligoarthritis	54%	20%	10%	10%	3%		2%
polyarthritis	62%	10%	13%	9%	4%	1%	1%
Grand Total	51%	25%	10%	9%	3%	0%	2%

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POS1058

SUBCLINICAL DACTYLITIS: COMPARATIVE STUDY OF THERAPEUTIC RESPONSE WITH TNF INHIBITORS, SECUKINUMAB AND USTEKINUMAB

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Background: Non tender dactylitis has been recently associated with synovitis, tenosynovitis and enthesitis without fat tissue hyperemia. Dactylitis is a remarkable hallmark of spondyloarthritis and particularly in psoriatic arthritis. Also, dactylitis has been recognized as one of the most difficult musculoskeletal feature of the disease to treat. It has been of interest to compare the effectiveness of available therapies in cases of clinical dactylitis, however, the efficacy on subclinical dactylitis has not studied yet.

Objectives: To determine the effectiveness of three different biological therapy approaches in subclinical (non-tender) dactylitis in patients diagnosed by psoriatic arthritis in terms of changes detected by ultrasound scan.