multivariable models, biologic-experienced patients were more likely to discontinue treatment (HR 1.21 [95% CI 1.04–1.43]; $p=0.017$) vs. biologic-naïve patients, while PsA had no significant effect on TTD alone vs. no PsA (HR 1.12 [95% CI 0.9–1.4]; $p=0.31$). However, comorbid PsA increased the likelihood of treatment discontinuation for biologic-experienced patients (HR 1.45 [95% CI 1.06–1.97]; $p=0.018$). Obesity was a further predictor of discontinuation (HR 1.15 [95% CI 1.02–1.31]; $p=0.027$) and this was independent of comorbid PsA and prior biologic exposure (Table 1).

Conclusion: Comorbid PsA was associated with reduced time-to-discontinuation of UST in biologic-experienced patients, but not biologic-naïve patients. Obesity also impacted TTD but independently of PsA status.

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Table 1. Multivariate analysis of UST discontinuation in PsO patients (N=3,174).

Covariate	Status (n)	HR	95% CI	p-value
Comorbid PsA	No PsA	ref	-	-
	(n=2609) PsA	1.12	0.90–1.40	0.31
Biologic experience	(n=565) No prior biologic (n=2371)	ref	-	-
	Prior biologic (n=803)	1.21	1.04–1.43	0.017
PsA*prior biologic experience	No PsA, prior biologic	ref	-	-
	(n=539) PsA, prior biologic	1.45	1.06–1.97	0.018
Obesity (BMI, kg/m ²)	(n=264) <30	ref	-	-
	(n=1554) ≥30	1.15	1.02–1.31	0.027
	(n=1620)			

BMI, body mass index; CI, confidence interval; HR, hazard ratio; PsA, psoriatic arthritis; PsO, psoriasis; ref, reference; UST, ustekinumab.

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POS1053

COMPARISON OF BASELINE CHARACTERISTICS BETWEEN PATIENTS CONTINUING OR DISCONTINUING APREMILAST AT TWELVE MONTHS IN THE REWARD STUDY (THE NETHERLANDS)

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Background: Previous analysis of the REWARD study reported that patients with limited joint involvement have a considerable burden of disease¹. Recent data suggest that patients with moderately active psoriatic arthritis (PsA) and a limited joint involvement have a high likelihood of achieving treatment goals when treated with apremilast². According to EULAR recommendations a PDE4 inhibitor may be considered in patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAK inhibitor is appropriate and the value of apremilast may be found in treating patients with relatively mild disease (oligoarticular)³.

Objectives: The objective of this prospective, multicentre, non-interventional study is to describe patient reported outcomes, effectiveness and real-life use of

apremilast in patients with PsA. Patients will be followed up for a maximum of 12 months. This interim analysis compared the baseline characteristics and experience on apremilast for two subgroups of patients, those remaining on apremilast versus the ones that discontinued.

Methods: In this interim analysis we included patients with data available at cut-off date of 03 November 2020. Patient enrollment and follow up of current subjects is ongoing. Descriptive statistics (n's and percents for categorical data, means for continuous data) were used to summarize the baseline data by subgroup. Kaplan Meier plots are presented to show patients' experience on apremilast by subgroup.

Results: 85 patients were included in the analysis. 30 patients have completed the study, 39 patients have discontinued and 16 are ongoing. At baseline 22 (26%) patients were biologic experienced and 62 (74%) were biologic naïve. Both groups had a comparable disease activity measured with clinical disease activity in psoriatic arthritis (cDAPSA) scores. Biologic experienced patients had a longer disease duration compared to biologic naïve patients (mean 9.7 vs 6.2 years). Inefficacy of previous medication was the main reason for starting apremilast in both subgroups. Overall, 86% (n=69) of patients were still receiving apremilast at month 3, 60% (n=46) at month 6, and 41% (n=26) at month 12 (Figure 1). Drug survival (length of time until discontinuation of apremilast) for biologic naïve patients was 93% at month 3, 73% at month 6 and 58% at month 12. Drug survival of biologic experienced patients was 67%, 20%, and 0% at months 3, 6, and 12, respectively. At baseline mean values of body mass index (BMI), swollen joint count (SJC), tender joint count (TJC), psoriatic arthritis impact of disease (PsAID) were comparable between both groups (Table 1). Reasons for discontinuation were mainly lack of efficacy (49%) and adverse events (44%). In this analysis the nature and frequency of adverse events is in line with the known profile of apremilast.

Conclusion: In this interim analysis, patients who were biologic naïve had a better probability to remain on treatment than those who were biologic experienced. Baseline characteristics were similar between the two groups, apart from disease duration that was longer in the biologic experienced group. Best drug survival is achieved when apremilast is prescribed earlier in the PsA treatment course, before biologics and after csDMARDs, as per apremilast EU label.

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POS1054

UPADACITINIB PHARMACOKINETICS AND EXPOSURE-RESPONSE RELATIONSHIPS FOR EFFICACY AND SAFETY IN PSORIATIC ARTHRITIS – ANALYSES OF THE PHASE 3 SELECT-PsA STUDIES

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Background: Upadacitinib (UPA) is an oral, reversible, JAK inhibitor approved for the treatment of rheumatoid arthritis (RA). The efficacy and safety profile of UPA in psoriatic arthritis (PsA) has been established in the SELECT-PsA program which includes two global Phase 3 studies.

Objectives: These analyses characterize UPA pharmacokinetics and exposure-response relationships for efficacy and safety endpoints using data from the SELECT-PsA studies.

Methods: The SELECT-PsA program enrolled patients with prior inadequate response (IR) or intolerance to ≥1 non-bDMARD1 (N=1705) and prior IR or intolerance to ≥1 bDMARD2 (N=642). Data from both trials was integrated for patients receiving placebo (PBO), UPA 15mg once daily (QD) and UPA 30mg QD; adalimumab data was excluded from this analysis. UPA pharmacokinetics were characterized in PsA patients using Bayesian population pharmacokinetics analyses and utilizing prior information from analyses in healthy subjects and RA patients. Exposure-response analyses were conducted using logistic regression to characterize the relationships between upadacitinib average plasma concentration during a dosing interval (C_{avg}) and the percentage of patients achieving

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