Table 1. Achievement of Key Outcomes Across PsA Manifestations at Week 104 Among TNFi-IR and TNFi-Naive Patients Treated With SEC

	SEC 300 mg		SEC 150 mg ^a		SEC 150 mg No Load ^b		PBO-SEC 300 mg		PBO-SEC 150 mg ^c	
Outcomes, n/M (%)	TNFi-naive n=154	TNFi-IR n=68	TNFi-naive n=153	TNFi-IR n=67	TNFi-naive n=157	TNFi-IR n=65	TNFi-naive n=109	TNFi-IR n=44	TNFi-naive n=114	TNFi-IR n=39
TJC/SJC resolution	51/140 (36.4)	19/51 (37.3)	46/136 (33.8)	11/46 (23.9)	53/125 (42.4)	14/43 (32.6)	40/90 (44.4)	11/31 (35.5)	32/96 (33.3)	10/28 (35.7)
Resolution of dactylitis	42/48 (87.5)	11/16 (68.8)	37/43 (86.0)	16/19 (84.2)	56/62 (90.3)	11/13 (84.6)	35/41 (85.4)	5/7 (71.4)	30/33 (90.9)	10/12 (83.3)
Resolution of enthesitis	70/88 (79.5)	22/30 (73.3)	70/85 (82.4)	24/32 (75.0)	50/69 (72.5)	16/26 (61.5)	37/50 (74.0)	12/17 (70.6)	39/56 (69.6)	14/20 (70.0)
mNAPSI75	61/73 (83.6)	15/26 (57.7)	66/76 (86.8)	16/23 (69.6)	61/80 (76.3)	13/18 (72.2)	42/51 (82.4)	13/17 (76.5)	34/64 (53.1)	7/14
PASI100	34/68 (50.0)	14/29 (48.3)	41/85 (48.2)	5/19 (26.3)	33/73 (45.2)	4/18 (22.2)	23/45 (51.1)	9/18 (50.0)	19/46 (41.3)	(50.0) 6/13 (46.2)

IR, inadequate responder; M, number of evaluable patients; mNAPSI, modified Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index; PBO, placebo; SEC, secukinumab; TJC/SJC resolution, 0 tender/swollen joints; TNFi, tumor necrosis factor inhibitor. ^a Includes 53 TNFi-naive and 23 TNFi-IR patients with dose escalation. ^b Includes 58 TNFi-naive and 19 TNFi-IR patients with dose escalation. ^c Includes 40 TNFi-naive and 12 TNFi-IR patients with dose escalation.

Background: The goal of treating psoriatic arthritis (PsA) is to achieve very low disease activity or remission across disease manifestations. In the phase 3 FUTURE 5 study (NCT02404350), patients receiving secukinumab (SEC) demonstrated sustained clinical improvements across PsA manifestations through Week 104.¹ However, the effect of previous tumor necrosis factor inhibitor (TNFi) exposure on achievement of remission across PsA manifestations was not explored.

Objectives: To report exploratory efficacy analyses of SEC at Week 104 on stringent endpoints across PsA manifestations in patients who were TNFi naive or inadequate responders (TNFi-IR).

Methods: Patient data from FUTURE 5 were stratified by previous TNFi exposure and analyzed by treatment arm. At Week 104, patients received SEC 300 or 150 mg with subcutaneous loading dose (LD), SEC 150 mg without LD, or had received placebo up to Week 16 and were switched to SEC 300 or 150 mg between Weeks 16 or 24 based on tender and swollen joint count response. Patients with suboptimal clinical response to SEC 150 mg could escalate to SEC 300 mg after Week 52 per investigator judgment.² Exploratory efficacy analyses at Week 104 included resolution of TJC/SJC (0 tender/swollen joints), resolution of enthesitis and dactylitis, 75% improvement in the modified Nail Psoriasis Severity index (mNAPSI75), 100% improvement in the Psoriasis Area and Severity Index (PASI100), very low disease activity (VLDA), and Disease Activity in Psoriatic Arthritis (DAPSA) remission. Descriptive statistics are provided for each endpoint using an observed-case approach.

Results: Regardless of previous TNFi exposure, SEC-treated patients achieved several stringent endpoints across PsA domains, including TJC/SJC resolution, resolution of dactylitis/enthesitis, mNAPSI75, and PASI100 at Week 104 (Table 1). TNFi-naive patients generally experienced greater improvements than TNFi-IR patients (Table 1 above). Similar trends were observed for achievement of VLDA and DAPSA remission at Week 104 (Figure 1).

Conclusion: SEC treatment resulted in sustained achievement of stringent endpoints across key PsA manifestations through Week 104 in both TNFi-naive and TNFi-IR patients, with generally greater clinical responses among TNFi-naive patients.

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Figure. Proportion of Patients Achieving (A) VLDA and (B) DAPSA Remission at Week 104

DAPSA, Disease Activity in Psoriatic Arthritis; IR, inadequate responders; NL, no subcutaneous loading dose; PBO, placebo; SEC, secukinumab; VLDA, very low disease activity based on body surface area.

Figure 1.

POS1051 SECUKINUMAB IMPROVES PHYSICAL FUNCTION AND INHIBITS STRUCTURAL DAMAGE IN PsA PATIENTS WITH SUSTAINED REMISSION OR LOW DISEASE ACTIVITY: RESULTS FROM A PHASE 3 STUDY

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Background: Disease Activity Index for Psoriatic Arthritis (DAPSA) or the minimal disease activity (MDA) are considered for defining remission (REM) or low disease activity (LDA) in secukinumab (SEC) treated patients (pts) with PsA (Psoriatic Arthritis).¹ Currently, limited SEC data are available on pts with PsA achieving sustained REM in clinical trials or real-world evidence, using these stringent criteria.

Objectives: To report an exploratory analysis on achievement of sustained REM/LDA in pts with PsA treated with SEC and impact on structural outcomes, physical function and health-related quality of life (HRQoL) in the FUTURE 5 study (NCT02404350).

Methods: FUTURE 5 is a randomised, double-blind, placebo-controlled 2-year phase 3 trial in pts with active PsA.² Pts randomised to SEC 150 mg could be escalated to 300 mg from Week (Wk) 52 to 104, based on investigators' judgement. The pts were categorised as either not achieving REM/LDA, achieving it once only or sustained REM/LDA, which was defined as pts who achieved REM/LDA between Wks 24-52 and maintained the same response at least 2 of the next 6 visits (visit every 8 Wks). Of pts who did not achieve REM/LDA, achieved REM/LDA (VLDA, DAPSA REM, MDA, DAPSA LDA+REM) between Wk 24 and 52, the relationship between absence of REM/LDA, REM/LDA, sustained REM/LDA, proportion of pts with non-radiographic progression (assessed using the van der Heijde [mTSS]), physical function (health assessment questionnaire disability index [HAQ-DI]), and short form-36 physical component score [SF-36 PCS])³ were assessed.

Results: In total, 996 pts were randomised to one of 4 treatment groups: SEC 300 mg loading dose (LD; N=222), SEC 150 mg LD (N=220), SEC 150 mg no loading dose (NL; N=222), and placebo (N=332). The baseline clinical characteristics were comparable across treatment groups. Majority of pts could achieve either sustained MDA/sustained DAPSA LDA+REM (Figure 1). Pts achieving REM/LDA, whether at one visit or consistently, showed improved physical function and SF36-PCS at Wk 104.³ A high proportion of pts did not show radiographic progression at Wk 104 irrespective of achievement of REM/LDA category (Table 1).

Conclusion: The majority of patients treated with secukinumab were able to achieve sustained LDA. Sustained LDA/REM was associated with improved HRQoL, physical function and inhibition of structural damage progression.

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Figure 1. Proportion of patients achieving VLDA/MDA/DAPSA REM/DAPSA LDA+REM+LDA sustained REM/LDA was defined if the same response was achieved at least 2 out of the next 6 visits (every 8 weeks), respectively. DAPSA, Disease activity in Psoriatic Arthritis; LD, loading dose; LDA, Low Disease Activity; MDA, Minimal Disease Activity; N, number of randomised patients assessed at both Week 24 and 104; NL, without loading dose; REM, remission; SEC, secukinumab; VLDA, Very Low Disease Activity

Table 1. Percentage of vdH-mTSS no progression at Week 104 (change from baseline ≤ 0.5) by REM/LDA and sustained REM/LDA status

REM and LDA composite indices, n (%)	Treatment group	No REM/LDA	REM/LDA only once	Sustained REM/LDA
MDA	SEC 150 mg LD	64 (75.3)	16 (80.0)	76 (86.4)
	SEC 150 mg NL	56 (75.7)	15 (78.9)	69 (82.1)
	SEC 300 mg LD	58 (79.5)	19 (95.0)	100 (94.3)
VLDA	SEC 150 mg LD	108 (78.8)	15 (83.3)	30 (88.2)
	SEC 150 mg NL	95 (75.4)	13 (81.3)	32 (91.4)
	SEC 300 mg LD	115 (84.6)	17 (94.4)	45 (100.0)
DAPSA REM	SEC 150 mg LD	77 (76.2)	11 (78.6)	46 (92.0)
	SEC 150 mg NL	65 (71.4)	10 (76.9)	50 (87.7)
	SEC 300 mg LD	82 (83.7)	14 (93.3)	63 (96.9)
DAPSA LDA + REM	SEC 150 mg LD	29 (70.7)	16 (84.2)	80 (84.2)
	SEC 150 mg NL	23 (71.9)	15 (75.0)	79 (79.0)
	SEC 300 mg LD	39 (88.6)	21 (84.0)	97 (89.0)

Sustained REM/LDA was defined if the same response was achieved at least twice out of the next 6 visits (every 8 weeks), respectively. n, number of evaluable patients; vdH-mTSS, van der Heijde- modified total Sharp score

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POS1052 PSORIATIC ARTHRITIS AND OBESITY IMPACT DRUG PERSISTENCE IN USTEKINUMAB-TREATED PATIENTS WITH PSORIASIS IN THE BRITISH ASSOCIATION OF DERMATOLOGISTS BIOLOGIC AND IMMUNOMODULATORS REGISTER (BADBIR): A 10-YEAR FOLLOW-UP STUDY

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Background: Up to 80% of patients with psoriatic arthritis (PsA) have comorbid psoriasis (PsO).¹ However, data on the impact of comorbid PsA on treatment persistence in PsO patients are limited with mixed findings.²⁻⁴ Other factors have been implicated in predicting response to treatment, including obesity, which is associated with PsA and has demonstrated a varying effect on biologic persistence.^{2,3,5,6}

Objectives: The primary objective of this study was to evaluate whether comorbid PsA and obesity impact ustekinumab (UST) persistence in PsO patients using the British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR). Additionally, the effect of line of therapy was investigated.

Methods: This retrospective observational study used data from PsO patients receiving UST in the BADBIR (first enrolled 07/2009; 10/2020 data cut-off). Time to discontinuation (TTD) was defined as time from treatment start date until treatment stop date, censoring for loss to follow-up where patients are lost to follow-up or active in the registry without a recorded treatment stop date. Kaplan-Meier survival analysis was used to estimate probability of discontinuation over time and median TTD. Patients were stratified by PsA diagnosis (recorded as a comorbidity at enrolment) and prior biologic experience (history of treatment with ≥ 1 other biologic). The log-rank test was used to compare persistence among groups. Hazard ratios (HRs), confidence intervals (CI) and p-values for effect of obesity, PsA status and prior biologic exposure on TTD were generated using Cox proportional hazards regression.

Results: Univariate analysis found that median TTD was shorter for patients with comorbid PsO and PsA (5.04 years; n=585) vs. patients with PsO alone (7.19 years; n=2698; p<0.0001). Biologic-experienced patients with comorbid PsO and PsA (n=292) had a significantly higher likelihood of discontinuation than any other group, with a median TTD of 3.84 years (p<0.0001; Figure 1). In

Fig. 1: Drug survival in patients with PsO treated with UST, stratified by presence of comorbid PsA and prior biologic experience.

p-value for drug survival probability across all groups. PsA, psoriatic arthritis; PsO, psoriasis; UST, ustekinumab.