Abstract THU0324 – Table 1. Patient Characteristics by Prevalent Comorbidity at Registry Entry

	Yes (n=201)	CVD No (n=1292)	P	Yes (n=227)	MetS ^a No (n=1266)	P	Yes (n=177)	Cancer No (n=1316)	P
Women	44.3%	52.7%	0.03	50.7%	51.8%	0.8	55.7%	51.0%	0.3
Age, y	62.5	53.0	<0.001	61.8	52.9	<0.001	61.9	53.2	<0.001
Employed full-time ^b	33.5%	58.6%	<0.001	36.2%	58.6%	<0.001	39.4%	57.3%	<0.001
Private insurance	61.9%	81.4%	<0.001	60.6%	82.0%	<0.001	68.6%	80.1%	<0.001
Obese ^b	61.0%	52.8%	0.1	92.0%	46.8%	<0.001	51.2%	54.3%	0.7
Clinical disease activity index	11.8	11.7	0.9	11.9	11.7	0.7	11.1	11.8	0.4
Tender joint count	4.42	4.37	0.9	5.16	4.23	0.1	4.33	4.38	0.9
Swollen joint count	2.58	1.96	0.045	2.50	1.96	0.07	1.76	2.08	0.3
Physician global assessment	17.7	16.4	0.4	16.7	16.5	0.9	15.7	16.6	0.5
Patient global assessment	51.7	57.8	0.01	50.7	58.1	<0.001	52.3	57.6	0.03
% body surface area	7.1	5.1	0.02	6.6	5.1	0.07	5.3	5.4	0.9
Enthesitis	26.4%	26.9%	0.9	26.9%	26.8%	0.9	28.3%	26.6%	0.6
Dactylitis	14.9%	12.9%	0.4	17.2%	12.5%	0.054	9.0%	13.8%	0.08
Nail visual analogue scale	8.0	7.1	0.5	7.3	7.2	0.9	6.4	7.3	0.5

THU0325

SECUKINUMAB DEMONSTRATES A CONSISTENT SAFETY PROFILE WITH UP TO 5 YEARS TREATMENT IN PATIENTS WITH PSORIATIC ARTHRITIS AND MODERATE TO SEVERE PLAQUE PSORIASIS: UPDATED POOLED SAFETY ANALYSES

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Background: Pooled safety data from secukinumab (SEC) studies in psoriasis and psoriatic arthritis (PsA) have been reported previously.¹

Objectives: To report updated longer-term safety data with up to 5 years of SEC treatment from psoriasis and PsA studies.

Methods: The moderate to severe plaque psoriasis and active PsA data pool consisted of 15 and 3 Phase III studies, respectively. Different SEC doses in the studies included intravenous (up to 10 mg/kg) or subcutaneous (s.c.; 75–300 mg) loading, followed by s.c. maintenance dosing (300, 150 or 75 mg). Placebo patients were re-randomised to SEC at 12–24 weeks depending on study design. Adverse events (AEs) were reported as exposure adjusted incident rates (EAIR) per 100 patient-years and analyses included all patients who received ≥1 dose of SEC.

Results: A total of 5181 and 1380 patients from psoriasis and PsA studies representing an exposure of 10416.9 and 3866.9 patient years, respectively, were included in this study. The most frequently reported AE was viral upper respiratory tract infection (table 1). EAIRs for serious infections, *Candida* infections, inflammatory bowel disease (IBD) and major adverse cardiac events (MACE) were low and similar in both psoriasis and PsA indications (table 1). No cases of tuberculosis were reported.

Abstract THU0325 – Table 1. Summary of Secukinumab Safety across Psoriasis and PsA studies: Entire Safety Period

	Psoriasis Any secukinumab n=5181	PsA Any secukinumab n=1380
Total exposure, patient-years	10416.9	3866.9
Min-max exposure (days)	1–1825	8–1827
Exposure (days), mean (SD)	734.4 (562.9)	1023.5 (472.3)
Death, n (%)	9 (0.2)	11 (0.8)
EAIR per 100 Patient-years (95% CI)		
Any AE	204.4 (198.4, 210.5)	147.0 (138.9, 155.5)
Any serious AE	6.9 (6.3, 7.4)	7.9 (7.0–8.9)
Most Common AEs¹		
Viral upper respiratory tract infection	21.0 (19.9–22.0)	12.1 (10.9–13.4)
Headache	6.2 (5.8, 6.8)	3.8 (3.2, 4.5)

Upper respiratory tract infection	5.4 (4.9, 5.9)	9.1 (8.1, 10.2)
AEs of Selected Interest		
Serious infections ²	1.4 (1.2, 1.6)	1.9 (1.5, 2.4)
<i>Candida</i> infections ³	2.2 (1.9, 2.5)	1.5 (1.1, 2.0)
IBD ⁴	0.01 (0.0–0.05)	0.05 (0.01–0.19)
Crohn's disease ⁴	0.05 (0.02–0.11)	0.08 (0.02–0.23)
Ulcerative colitis ⁴	0.13 (0.07–0.23)	0.08 (0.02–0.23)
MACE ⁵	0.3 (0.2, 0.5)	0.4 (0.3–0.7)

¹AEs in the SEC group that occurred with an EAIR of ≥5 during the entire safety period in either of the pooled groups; ²Rates are for system organ class; ³Rates are for high level term; ⁴Rates are for PT (IBD PT data are reported for unspecified IBD); ⁵Rates are for Novartis MedDRA Query term; EAIR, exposure adjusted incidence rate per 100 patient-years; N, number of patients in the analysis; SD, standard deviation

Conclusions: SEC demonstrated a favourable safety profile during long-term treatment (up to 5 years) in patients with moderate to severe plaque psoriasis or PsA, hence, supporting long-term use. The safety profile was consistent with previous reports and comparable across psoriasis and PsA patients.

REFERENCE:

[1] Mease, et al. Arthritis Rheumatol 2017; 69(suppl 10):A606.

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THU0326

DISCONTINUATION AND SWITCHING PATTERNS OF TUMOUR NECROSIS FACTOR INHIBITOR (TNFI) THERAPY IN TNFI-NAÏVE AND TNFI-EXPERIENCED PATIENTS WITH PSORIATIC ARTHRITIS IN THE US CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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Background: To better inform treatment decisions for patients with psoriatic arthritis (PsA), it is important to understand outcomes in patients who initiate a first line vs a subsequent line of TNFi therapy. Limited studies have evaluated persistence and switching of TNFi therapy in TNFi-naïve vs TNFi-experienced US patients with PsA.

Objectives: To examine discontinuation and switching of TNFis in TNFi-naïve and -experienced patients with PsA in the US Corrona PsA/SpA Registry.

Methods: All patients aged ≥ 18 years in the Corrona PsA/SpA Registry who were diagnosed with PsA, initiated a TNFi (index therapy) between March 2013 and , January 2017 and had ≥ 1 follow-up visit after TNFi initiation were included. Patients were stratified by prior TNFi use (TNFi naïve: no prior TNFi or other biologic; TNFi experienced: ≥ 1 prior TNFi). Patient demographics and clinical and disease characteristics were assessed at the time of TNFi initiation (baseline). Time to discontinuation of the index TNFi (with or without switching) and time to switch to another biologic were assessed by Kaplan-Meier analysis. Log-rank tests were used to assess differences in persistence and switching between the TNFi-naïve and -experienced cohorts. Provider-reported reasons for discontinuation of the index TNFi were summarised descriptively.

Results: 318 patients with PsA were included (TNFi naïve, n=171; TNFi experienced, n=147), with a total follow-up of 579.2 person-years. Experienced patients had a longer mean (SD) disease duration (13.3 [10.0] vs 9.5 [9.7] years; $p < 0.01$) and a higher proportion had a history of prednisone use (27.9% vs 17.5%; $p = 0.03$) compared with naïve patients. A total of 75 naïve (43.9%) and 80 experienced patients (54.4%) discontinued their index TNFi, including 33 (19.3%) and 48 (32.7%), respectively, who switched to a new biologic. The median (95% CI) time to discontinuation of the index TNFi in naïve vs experienced patients was 27 (22 to 33) vs 20 (18 to 28) months, respectively (figure 1). Among those who discontinued their TNFi, the mean (SD) time to discontinuation was 14.5 (8.0) months in naïve patients vs 14.0 (8.9) months in experienced patients. Due to the low number of switching events, the median time to switch of the index TNFi could not be estimated. Among those who switched to a new biologic, the mean (SD) time to switch was 16.0 (8.1) vs 13.5 (7.5) months in naïve and experienced patients, respectively. TNFi-naïve patients had greater persistence with their index TNFi ($p = 0.03$) and were less likely to switch to another biologic ($p = 0.002$) compared with TNFi-experienced patients. Provider-reported reasons for discontinuation included lack of effect (naïve, 71%; experienced, 62%), side effects (10%; 23%), social reasons (6%; 3%), doing well (3%; 0%), and other (10%; 12%).

Abstract THU0326 – Figure 1. Time to Discontinuation (With or Without Switching) and Time to Switch of Index TNFi in TNFi-Naïve and TNFi-Experienced Patients With PsA. PsA, psoriatic arthritis; TNFi, tumour necrosis factor inhibitor.

Conclusions: In this real-world analysis of US patients with PsA, TNFi-experienced patients were more likely to discontinue and switch their index TNFi and had a shorter time to discontinuation compared with TNFi-naïve patients. These results may help inform treatment decisions when selecting later lines of TNFi therapy in patients with PsA.

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THU0327

REAL WORLD (RW) EXPERIENCE WITH AN ANTI-IL-17A INHIBITOR IN BIOLOGIC NAÏVE AND BIOLOGIC EXPERIENCED PSORIATIC ARTHRITIS (PSA) PATIENTS

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Background: Two IL-17A inhibitors are approved for the treatment of PsA, ixekizumab and secukinumab. At the time of this survey, real world evidence was only available for secukinumab, which was approved for PsA in 2016 in EU, Australia and Switzerland. Secukinumab label dose for PsA patients with either concomitant moderate to severe plaque psoriasis or anti-TNF α inadequate responders is 300 mg. For other patients, the recommended dose is 150 mg. All patients receive a loading dose regimen by S.C. injection at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dose. Little data are published on the RW utilisation of secukinumab in PsA.

Objectives: Describe RW dose utilisation of an anti-IL-17A inhibitor, among biologic naïve and biologic experienced PsA patients.

Methods: Data from a chart review study conducted in 2017 across France, Germany, Italy, Spain, UK, Australia and Switzerland where secukinumab is reimbursed were used. Specialists were recruited by field-based interviewers, and provided information on demographics, Body Surface Area (BSA), time since diagnosis and treatment for their adult PsA patients currently receiving secukinumab.

Results: 212 rheumatologists, 89 dermatologists, 1 orthopedist provided data for 1451 patients. Mean age 50.6 years, 47% female, mean time since PsA diagnosis 5.9 years and 86% had concomitant psoriasis. 96% received prior csDMARD(s) and 8% prior apremilast. 29% (425) were biologic naïve and 71% (1024) biologic experienced (limited differences between specialists: 74% rheumatologists; 63% dermatologists). 34%, 24%, and 13% received, 1, 2, and 3+ prior biologics respectively.

Among biologic naïve patients on 150 mg, 36% (52/145) had a BSA $\geq 10\%$, where the recommended dose is 300 mg at secukinumab initiation. 29% (274/930) of biologic experienced patients received secukinumab at 150 mg, not the recommended 300 mg dose (figure 1)

Abstract THU0327 – Figure 1. Secukinumab Dosing: Current Dose (Loading or Maintenance). *For this analysis, moderate to severe psoriasis was defined as BSA $\geq 10\%$

Conclusions: In the RW, secukinumab is prescribed mainly in biologic experienced patients (71%) and is not universally prescribed at the recommended dose for PsA. Specifically, of those who are biologic naïve (29%), 36% of patients on 150 mg had moderate to severe psoriasis, which is outside the recommended dose. Further RW experience is needed for ixekizumab.

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