[4] Helliwell PS et al, Ann Rheum Dis. 2013;72:986–91.
Disclosure of Interest: L. Coates Grant/research support from: Abbvie, Janssen, Consultant for: Abbvie, BMS, Celgene, Pfizer, UCB, MSD, Novartis, Lilly, Janssen, Sun Pharma, D. Gladman Grant/research support from: Amgen, AbbVie, BMS, Celgene, Eli Lilly, Janssen, Novartis, Pfizer and UCB, P. Nash Grant/research support from: Novartis, Abbvie, Roche, Pfizer, BMS, Janssen, and Celgene, Consultant for: Novartis, Abbvie, Roche, Pfizer, BMS, Janssen, and Celgene, Speakers bureau: Novartis, Abbvie, Roche, Pfizer, BMS, Janssen, and Celgene, O. Fitzgerald Grant/research support from: Bristol-Myers Squibb, Roche, Abbott, Consultant for: Bristol-Myers Squibb, Roche, Abbott, A. Kavanaugh Consultant for: Novartis, L. Rasouliyan Consultant for: Novartis through employment at RTI Health Solutions, Employee of: RTI Health Solutions, L. Pricorp Shareholder of: Novartis, Employee of: Novartis, K. Ding Shareholder of: Novartis, Employee of: Novartis, C. Gaillez Shareholder of: Novartis, BMS, Employee of: Novartis
DOI: 10.1136/annrheumdis-2017-eular.1458

SAT0463 SECUKINUMAB PROVIDES SUSTAINED REDUCTION IN FATIGUE IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS THROUGH 3 YEARS: LONG-TERM DATA FROM THE FUTURE 1 AND FUTURE 2 STUDIES

L. Gossec[1], T.K. Kvien[2], P.G. Conaghan[3], M. Østergaard[4], D. Gladman[5], P. Mease[6], L. Rasouliyan[7], L. Pricop[8], C. Gaillez[9], S. Jugl[9]. *[1]UPMC University Paris 06, Paris, France; [2]Diakonhjemmet Hospital, Oslo, Norway; [3]University of Leeds, Leeds, United Kingdom; [4]Copenhagen Center for Arthritis Research (COPECARE), Glostrup, Denmark; [5]University of Toronto, Toronto, Canada; [6]Swedish Medical Center, Seattle, WA, United States; [7]RTI Health Solutions, Barcelona, Spain; [8]Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States; [9]Novartis Pharma AG, Basel, Switzerland*

Background: Fatigue, a common symptom in patients (pts) with PsA, can negatively impact HRQoL and social functioning. Secukinumab (SEC), a fully human anti–IL-17A mAb, rapidly improved signs and symptoms, physical functioning, HRQoL, and fatigue in pts with PsA.[1,2]
Objectives: To assess the long-term effects of SEC on fatigue in TNF inhibitor (TNF)-naïve PsA pts and those with an inadequate response or intolerance to TNF inhibitor therapy (TNF-IR).
Methods: 606 and 397 pts were randomized to SEC or placebo (PBO) in FUTURE 1 (10 mg/kg IV followed by 150 or 75 mg SC) and FUTURE 2 (300, 150, or 75 mg SC), respectively. At Wk 16, PBO pts with ≤20% reduction in tender/swollen joint count (non-responders) were re-randomized to SEC 150 or 75 mg SC (FUTURE 1) and SEC 300 or 150 mg SC (FUTURE 2); responders were re-randomized at Wk 24. Pts in FUTURE 1 could enter a LTE study at Wk 104 (NCT01892436). Across both studies, approximately 68% of pts were TNF-naïve and 32% were TNF-IR. Fatigue was assessed at baseline (BL) and Wks 4, 8, 12, 16, 24, 52, 104, and 156 (FUTURE 1 only) using FACIT-F (higher scores = less fatigue). Fatigue response was defined by an increase in FACIT-F score of ≥4 from BL (corresponding to the MCID). Correlations between BL characteristics and improvements in fatigue were investigated using a logistical regression model. Only data with approved doses of SEC (300/150 mg) are shown.
Results: FACIT-F was 27.8–28.9 and 26.6–29.2 at BL across groups in FUTURE 1 and 2, respectively. Improvements in fatigue seen with all doses of SEC vs. PBO from Wks 4–24 were sustained through 156 wks in FUTURE 1 and 104 wks in FUTURE 2 in both the overall population and subgroups stratified by prior exposure to TNF (Table). The numerically higher responses with SEC 150 vs. 300 mg in this observed analysis were as a result of a higher rate of discontinuation due to lack of efficacy with the lower dose, which inflated the response rate. In the overall population, the LS mean change (±SEM) from BL in FACIT-F was significantly greater with SEC vs. PBO at Wk 16 in both FUTURE 1 (7.25±0.72 vs. 4.07±0.76; P=0.002) and FUTURE 2 (300 mg: 5.89±0.92 vs. 1.86±0.93, P=0.002; 150 mg: 7.40±0.90 vs. 1.86±0.93, P<0.0001); improvements were sustained throughout the entire follow up in both studies (FUTURE 1 Wk 156: 6.14±0.77; FUTURE 2 Wk 104: 300 mg 7.29±1.04, 150 mg 7.02±1.06). Improvements were generally somewhat larger in TNF-naïve pts than in TNF-IR pts. Correlation analyses did not identify any BL factors that consistently predicted change in fatigue score across Wks 16, 52, and 104.

Table. FACIT-Fatigue responders in FUTURE 1/FUTURE 2 until Week 156/104[a]

Proportion of Patients with FACIT-Fatigue Response[b], % (n/m)	FUTURE 1[c]	FUTURE 2	
	SEC IV–150 mg	SEC 300 mg	SEC 150 mg
Overall Population	**N=161**	**N=100**	**N=100**
Week 16	60.4 (96/159)	50.5 (48/95)	70.0 (70/100)
Week 52	66.9 (107/160)	60.2 (56/93)	68.5 (61/89)
Week 104	63.4 (90/142)	62.4 (53/85)	70.1 (54/77)
Week 156	57.4 (89/155)	–	–
TNF-naïve	**N=120**	**N=67**	**N=63**
Week 16	61.3 (73/119)	52.4 (33/63)	71.4 (45/63)
Week 52	69.2 (83/120)	60.7 (37/61)	72.9 (43/59)
Week 104	63.9 (69/108)	60.7 (34/56)	71.7 (38/53)
Week 156	58.3 (67/115)	–	–
TNF-IR	**N=41**	**N=33**	**N=37**
Week 16	57.5 (23/40)	46.9 (15/32)	67.6 (25/37)
Week 52	60.0 (24/40)	59.4 (19/32)	60.0 (18/30)
Week 104	61.8 (21/34)	65.5 (19/29)	66.7 (16/24)
Week 156	55.0 (22/40)	–	–

[a]Observed data are shown; [b]Defined as improvement ≥4.0 points; [c]Data shown are from patients who entered the FUTURE 1 long-term extension study at Week 104
m, number of patients with sufficient data for evaluation; N, number of patients randomized to SEC 150 mg or SEC 300 mg (FUTURE 2 only); n, number of responders.

Conclusions: SEC-treated PsA pts achieved rapid, sustained, and clinically meaningful improvements in fatigue for up to 156 wks, with higher responses in TNF-naïve pts.
References:
[1] McInnes et al. Lancet 2015;386:1137–46.
[2] Mease et al. N Engl J Med 2015;373:1329–39.
Disclosure of Interest: L. Gossec Grant/research support from: BMS, Lippy, Pfizer; Consultant for: Abbvie, BMS, Celgene, Janssen, MSD, Novartis, Pfizer, Roche and UCB, T. Kvien Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly, Epirus, Janssen, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz and UCB, Speakers bureau: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly, Epirus, Janssen, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz and UCB, P. Conaghan Consultant for: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, Speakers bureau: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, M. Østergaard Consultant for: Abbvie, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merck, Novartis, Orion, Pfizer, Regeneron, Roche, UCB, Speakers bureau: Abbvie, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merck, Novartis, Orion, Pfizer, Regeneron, Roche, UCB, D. Gladman Grant/research support from: Abbvie, Amgen, BMS, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, UCB, Consultant for: Abbvie, Amgen, BMS, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, UCB, P. Mease Grant/research support from: Abbvie, Amgen, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merch, Novartis, Pfizer, SUN, UCB, Consultant for: Abbvie, Amgen, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merch, Novartis, Pfizer, SUN, UCB, Speakers bureau: Abbvie, Amgen, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merch, Novartis, Pfizer, SUN, UCB, L. Rasouliyan Consultant for: Novartis, L. Pricop Shareholder of: Novartis, Employee of: Novartis, C. Gaillez Shareholder of: Novartis and BMS, Employee of: Novartis, S. Jugl Shareholder of: Novartis, Employee of: Novartis
DOI: 10.1136/annrheumdis-2017-eular.1719

SAT0464 THE IDEAL TARGET FOR PSORIATIC ARTHRITIS? COMPARISON OF REMISSION AND INACTIVE DISEASE STATES IN A REAL LIFE COHORT

L.J.J. Van Mens[1], A.W.R. van Kuijk[2], D.L. Baeten[1,3], L.C. Coates[4]. *[1]AMC; [2]Reade, Amsterdam Immunology and Rheumatology Center, Amsterdam, Netherlands; [3]UCB, Brussels, Belgium; [4]LIRMM, University of Leeds, Leeds, United Kingdom*

Background: Recommendations on psoriatic arthritis (PsA) state that the target of treatment should be remission or inactive disease. Multiple potential targets have been developed and proposed, each with a different composition of clinical measurements.
Objectives: Our aim is to use an existing real life dataset of a large group of patients in a low disease activity state, to compare different targets and provide further evidence to choose a target.
Methods: This analysis uses data from a cross-sectional real life cohort of 250 PsA patients (EULAR16–2124). All patients were considered in an acceptable disease state according to the treating rheumatologist, defined by the fact that the rheumatologist did not consider to modify the current treatment. Remission/inactive disease targets were the DAPSA [TJC; SJC; patient global visual analogue scale (Pt VAS); pain VAS; CRP] and clinical (c)DAPSA [DAPSA minus CRP] remission (≤4), very low disease activity (VLDA) [7/7 of TJC ≤1; SJC ≤1; PASI ≤1; Pt pain ≤15mm; Pt VAS ≤20mm; HAQ ≤0.5; tender entheseal points ≤1], and PASDAS ≤1.9 or near remission (NR).
Results: 113 pts were in cDAPSA remission, 107 in DAPSA remission, 56 met VLDA and 37 in PASDAS NR. There was a very high percentage exact agreement between DAPSA and cDAPSA (96%) reflecting the similarity of the two definitions. DAPSA/cDAPSA and VLDA show a high correlation (pearson of 0,611 and 0,590 resp) but VLDA is more stringent in comparison with both DAPSA scores. The correlation between NR and DAPSA/cDAPSA/VLDA was lower, (pearson 0,400, 0,403 and 0,412 resp). Again PASDAS NR was generally more stringent than DAPSA/cDAPSA remission but greater dissimilarities are seen between PASDAS NR and VLDA where 14 patients are in VLDA but not PASDAS NR and 29 are in PASDAS NR but not VLDA.
Although presence of active joint disease was similar across the different measures, VLDA presents as a more stringent cutoff with less residual disease in PASI, TJC and less impact on DLQI and HAQ. All targets had similar % of patients