

Abstract AB0765 – Table 1. Core components by DAPSA states with secukinumab or placebo at Wk 16

Mean ± SD	SJC (66)		TJC (68)		PtGA (cm)		PP (cm)		CRP (mg/dl)	
	300mg/150mg	PBO	300mg/150mg	PBO	300mg/150mg	PBO	300mg/150mg	PBO	300mg/150mg	PBO
REM*	0.4±0.7/0.2±0.4	1.0±1.4	0.2±0.4/0.3±0.5	0.5±1.0	0.6±0.5/0.6±0.5	0.6±0.6	0.7±0.7/0.7±0.4	0.8±0.6	0.3±0.3/0.5±0.4	0.2±0.2
LDA [^]	1.7±2.3/1.4±1.6	1.6±2.0	2.5±1.9/1.8±2.2	2.3±2.7	2.3±1.6/2.1±1.2	2.3±1.8	2.3±1.3/2.3±1.3	2.6±1.8	0.4±0.4/0.4±0.7	0.2±0.3
MDA [#]	4.5±3.8/4.9±3.0	4.9±3.4	6.0±4.1/7.0±2.8	7.5±4.1	3.8±2.3/3.9±1.9	3.9±1.8	4.1±2.0/3.8±1.8	4.5±1.8	0.4±0.4/0.9±1.0	0.7±1.2
HDA [§]	10.7±7.5/14.4±11.1	10.4±7.2	24.6±12.4/29.2±19.0	26.6±15.2	4.9±1.7/5.6±2.0	5.9±1.8	5.2±1.9/5.6±1.8	6.1±1.5	0.4±0.4/0.6±0.7	1.2±1.7

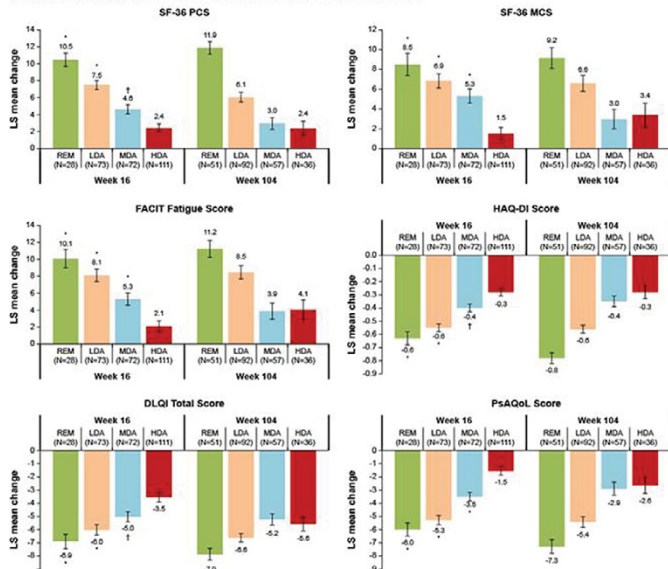
*n=14 (300mg), 10 (150mg) and 4 (PBO); [^]n=27 (300mg), 34 (150mg) and 12 (PBO); [#]n=26 (300mg), 24 (150mg) and 22 (PBO); [§]n=30 (300mg), 32 (150mg) and 49 (PBO).

Objectives: To explore the relationship between DAPSA states and function, health-related quality of life and PROs, and the individual DAPSA components in the different states in pts treated with secukinumab through 104 wks using *post-hoc* analysis.

Methods: FUTURE 2 study design has been reported.³ DAPSA was derived as sum of five core components: tender joint and swollen joint counts (TJC 68, SJC 66), pt global assessment (PtGA) and pain (PP) assessed by a 10cm VAS and CRP (mg/dl). Four DAPSA states were: remission (REM:≤4), low (LDA:>4–≤14), moderate (MDA:>14–≤28) or high disease activity (HDA:>28). Mean±SD of each core component of DAPSA were analysed at Wks 16, 24, 52 and 104 using observed data. The relationship between HAQ-DI, SF-36 PCS and MCS, PsAQoL, DLQI and FACIT-Fatigue with DAPSA states was assessed in the pooled treatment arms at each time point using a mixed-effect model for repeated measures (MMRM) analyses.

Results: Baseline characteristics were similar across treatment groups.³ DAPSA scores at baseline (mean±SD) were 42.0±17.4, 46.8±24.3 and 44.9±25.3 in the secukinumab 300mg, 150mg and placebo groups, respectively. Mean scores of each component by DAPSA states at Wk 16 are shown in table and were sustained through Wk 104. Significant differences were observed among secukinumab treated pts between REM vs. HDA and LDA vs. HDA states for PRO scores through Wk104 (Figure).

Figure: Mean change in PRO scores by DAPSA states at Wks 16 and 104



*P<.0001; [^]P<.001; [#]P<.001; [§]P<.05 versus HDA. P-values are from a mixed-effects model for repeated measures (MMRM) analysis.
DLQI, Dermatology Life Quality Index; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI, Health Assessment Questionnaire Disability Index; HDA, high disease activity; LDA, low disease activity; LS, least squares; PsAQoL, PsA-specific quality of life; MDA, moderate disease activity; REM, remission; SF-36 MCS, Short Form-36 Mental Component Summary; SF-36 PCS, Physical Component Summary

Conclusions: In pts treated with secukinumab 300 or 150mg, the five individual components related to DAPSA REM were <1 in contrast with other disease states and were sustained through Wk 104. DAPSA REM was associated with significantly greater improvement in physical function, health related quality of life and fatigue indicating that it is an important target to be achieved and sustained in PsA pts.

References:

- [1] Schoels MM, et al. Ann Rheum Dis 2016;75:811–8.
- [2] McInnes IB, et al. Arthritis Rheumatol 2016;68(suppl 10).
- [3] McInnes IB, et al. Lancet 2015;386:1137–46.

Disclosure of Interest: J. Smolen Grant/research support from: AbbVie, Janssen, Eli Lilly, MSD, Pfizer, Roche, Amgen, AstraZeneca, Astro, Celgene, Celltrion, GSK, ILTOO, Medimmune, Novartis-Sandoz, Pfizer, Samsung, Sanofi and UCB., Consultant for: AbbVie, Janssen, Eli Lilly, MSD, Pfizer, Roche, Amgen, AstraZeneca, Astro, Celgene, Celltrion, GSK, ILTOO, Medimmune, Novartis-Sandoz, Pfizer, Samsung, Sanofi and UCB., I. McInnes Grant/research support from: AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer and UCB, Consultant for: AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer and UCB, L. Gossec Grant/research support from: UCB, Eli Lilly and Pfizer; Consultant for AbbVie, BMS, Celgene, Janssen, Novartis, Pfizer and Roche, V. Strand Consultant for: AbbVie, Amgen, BMS, Celgene, Celltrion, Corrona, Genentech/Roche, GSK, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sanofi and UCB, L.

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DOI: 10.1136/annrheumdis-2017-eular.3648

AB0766 SECUKINUMAB PROVIDES SUSTAINED REMISSION AND LOW DISEASE ACTIVITY RELATED TO DISEASE ACTIVITY INDEX FOR PSORIATIC ARTHRITIS (DAPSA): 2 YEAR RESULTS FROM THE FUTURE 2 STUDY

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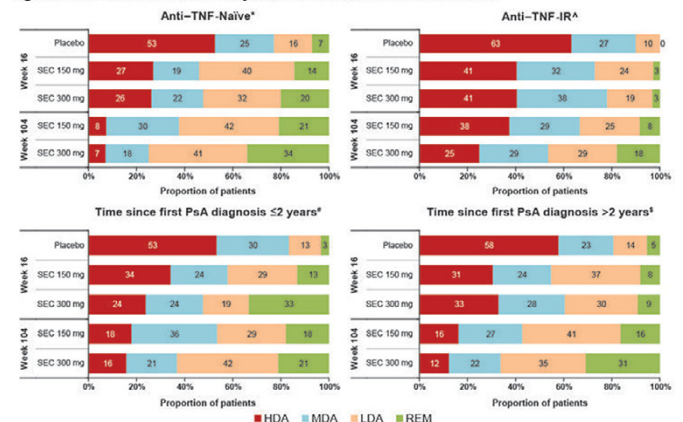
Background: Disease Activity Index for Psoriatic Arthritis (DAPSA) is a validated tool to measure disease activity states, focussing on peripheral joint involvement in psoriatic arthritis (PsA), and can be used to assess targets such as remission (REM) or low disease activity (LDA).¹

Objectives: Secukinumab, a fully human anti-interleukin-17A monoclonal antibody, significantly improved American College of Rheumatology responses vs. placebo at Week (Wk) 24 that were sustained through Wk 104 in active PsA patients (pts) in the FUTURE 2 study². This *post-hoc* exploratory analysis assessed DAPSA states through Wk 104.

Methods: In total, 397 active PsA pts were randomised to subcutaneous (s.c) secukinumab (300, 150 or 75mg) or placebo at baseline and Wks 1, 2, 3 and 4, and every 4 wks (q4w) thereafter. Placebo pts were re-randomised to secukinumab 300 or 150mg s.c q4w from Wk 16 or 24, depending on Wk 16 clinical response. DAPSA was derived as the sum of five variables: tender joint and swollen joint counts (TJC 68 and SJC 66); pt global and pain assessed on a 10cm visual analogue scale; and C-reactive protein levels (mg/dl) with validated cut-offs to indicate REM (≤4), LDA (>4 and ≤14), moderate disease activity (MDA; >14 and ≤28) and high disease activity (HDA; >28). DAPSA was assessed in the overall population and in pts stratified by prior anti-tumour necrosis factor (anti-TNF) therapy use (anti-TNF-naïve vs. inadequate response/intolerance to these agents [anti-TNF-IR]) and time since first PsA diagnosis (≤2 vs. >2 years) using observed data. Only data for secukinumab 300 and 150mg (approved doses) are reported.

Results: Baseline demographics and clinical characteristics were similar across treatment groups and previously reported.³ DAPSA score at baseline (mean [SD]) was 42.0 (17.4), 46.8 (24.3) and 44.9 (25.3) in the secukinumab 300mg, 150mg and placebo groups, respectively. In the overall population, at Wk 16, REM was achieved in 14/97 (14.4%) with secukinumab 300mg and 10/100 (10%) with secukinumab 150mg vs. placebo 4/87 (4.6%); LDA in 27/97 (27.8%) and 34/100 (34%) vs. 12/87 (13.8%), respectively. REM or LDA were sustained through Wk 104 with secukinumab 300 and 150mg (55/84 [65.5%]; REM + LDA) and 41/ 77 [53.2%]; REM + LDA, respectively). The proportion of pts achieving each DAPSA state at Wks 16 and 104 by anti-TNF status (anti-TNF-naïve vs. anti-TNF-IR)

Figure. DAPSA at Wks 16 and 104 by anti-TNF status and Disease duration



*n= 65 (300 mg), 63 (150 mg) and 57 (PBO) at Wk 16 and n= 56 (300 mg) and 53 (150 mg) at Wk 104; [^]n= 32 (300 mg), 37 (150 mg) and 30 (PBO) at Wk 16 and n= 28 (300 mg) and 24 (150 mg) at Wk 104; [#]n= 21 (300 mg), 38 (150 mg) and 30 (PBO) at Wk 16 and n= 19 (300 mg) and 28 (150 mg) at Wk 104; [§]n= 76 (300 mg), 62 (150 mg) and 57 (PBO) at Wk 16 and n= 65 (300 mg) and 49 (150 mg) at Wk 104

and by time since diagnosis (≤ 2 vs. > 2 years) for secukinumab 300 and 150mg is presented in the figure.

Conclusions: In the overall population, a higher proportion of pts treated with secukinumab at Wk 16 achieved DAPSA REM than those treated with placebo, with REM and LDA sustaining through Wk 104. At Wk 16, a higher proportion of anti-TNF-naïve pts treated with secukinumab achieved and sustained DAPSA REM than anti-TNF-IR pts and a higher proportion of pts with early diagnosis (≤ 2 years) achieved DAPSA REM vs. pts diagnosed later (> 2 years).

References:

- [1] Schoels MM, et al. *Ann Rheum Dis* 2016;75:811–8.
 [2] McInnes IB, et al. *Arthritis Rheumatol* 2016;68 (suppl 10).
 [3] McInnes, et al. *Lancet* 2015;386:1137–46.

Disclosure of Interest: J. Smolen Grant/research support from: AbbVie, Janssen, Eli Lilly, MSD, Pfizer, Roche, Amgen, AstraZeneca, Astro, Celgene, Celltrion, GSK, ILTOO, Medimmune, Novartis-Sandoz, Pfizer, Samsung, Sanofi and UCB., Consultant for: AbbVie, Janssen, Eli Lilly, MSD, Pfizer, Roche, Amgen, AstraZeneca, Astro, Celgene, Celltrion, GSK, ILTOO, Medimmune, Novartis-Sandoz, Pfizer, Samsung, Sanofi and UCB., I. McInnes Grant/research support from: AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer, and UCB., Consultant for: AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer, and UCB., Speakers bureau: AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer, 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., L. Pricop Shareholder of: Novartis, Employee of: Novartis, T. Fox Shareholder of: Novartis, Employee of: Novartis, L. Rasouliyan Consultant for: Novartis through employment at RTI, Employee of: RTI Health Solutions, S. Jugl Shareholder of: Novartis, Employee of: Novartis, C. Gaillez Shareholder of: Novartis and BMS, Employee of: Novartis

DOI: 10.1136/annrheumdis-2017-eular.4666

AB0767 IL-17-22-23 PATHWAYS IN PSORIATIC ARTHRITIS AND PSORIASIS

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Background: Psoriatic arthritis (PsA) is an immune-mediated chronic inflammatory arthropathy-associated with psoriasis. T helper 17 pathway has been shown to play an important role in PsA.

Objectives: In this study, we aimed to investigate concentrations of TH17 pathway cytokines such as IL-17, IL-22 and IL-23 in psoriasis (PsO) with/and without structural bone damage and psoriatic arthritis (PsA), and their relationship with disease activity and clinical findings.

Methods: A total number of 74 patients, 24 patients with PsA (mean age 57.5±11.37; 13 women, 11 men) and 25 patients with PsO and structural bone damage (mean age 49±13.92; 11 women, 14 men) and 25 patients with PsO and no structural bone damage (mean age 41±16.77; 7 women, 18 men), were recruited from the Department Internal Medicine 3 of the University of Erlangen-Nuremberg. Both PsO and PsA patients were evaluated according to the CASPAR criteria. Demographic and disease specific variables were recorded. Bone architecture of the metacarpal heads II and III were assessed by high-resolution peripheral quantitative computed tomography (HR-pQCT, XtremeCT, Scanco, Switzerland). Disease activity was assessed with Disease Activity Score (DAS28). Psoriatic skin and nail disease activity were measured by the PASI.

Results: The ages of the patients in the three groups were similar. IL-17A concentrations were significantly differed between the groups ($p=0.000$). However, for other cytokines there was no difference between PsA and PsO groups. Serum levels of IL-17A were significantly correlated to patient pain of VAS ($r=-0.318$, $p=0.06$), VAS patient global assessment ($r=0.272$, $p=0.021$), DAS28 ($r=-0.394$, $p=0.001$) and PASI ($r=0.519$, $p=0.000$) in PsA and PsO. PASI score were also positively correlated with IL23 ($r=-0.286$, $p=0.015$) and S100A8 ($r=0.298$, $p=0.011$).

Conclusions: IL-17A seems to play an important role in development of PsA and bone damage in PsO. This role should be elucidated by further and larger clinical studies.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.6768

AB0768 CLINICAL FEATURES OF RHEUMATOID FACTOR- OR ANTI-CYCLIC CITRULLINATED PEPTIDES-POSITIVE PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Although rheumatoid factor (RF) negativity is among the Classification Criteria for Psoriatic Arthritis (CASPAR) for the diagnosis of psoriatic arthritis (PsA), not all patients with PsA are seronegative. Measurement of anti-cyclic citrullinated peptides (ACPA) is another key test for rheumatoid arthritis and PsA; however, the prevalence of ACPA in patients with PsA is unclear.

Objectives: We analyzed the clinical features of RF- or ACPA-seropositive patients with PsA in comparison with seronegative patients with PsA using the ISLAND registry (UMIN000024292).

Methods: One hundred patients with psoriasis referred from dermatologists for assessment of synovitis or enthesitis from July 2015 to August 2016 were enrolled. PsA was diagnosed by CASPAR, and synovitis or enthesitis was confirmed by ultrasound assessment. Factors compared between seropositive and seronegative patients included age, sex, comorbidities, use of disease-modifying antirheumatic drugs, prevalence of enthesopathy, eye symptoms, duration between skin onset and musculoskeletal onset, psoriasis area severity index, composite psoriatic disease activity (CPDAI), psoriatic arthritis screening and evaluation (PASE), disease activity score-28 (DAS-28), and laboratory data.

Results: In total, 52 patients had PsA and 48 patients had psoriasis without any musculoskeletal manifestations. Significant differences were observed in the age at onset of psoriasis (37.4 vs. 47.9 y, respectively; $p<0.01$) and several clinical parameters (CPDAI: 14.60 vs. 4.55, respectively [$p<0.01$], PASE: 50.8 vs. 32.0, respectively [$p<0.01$], DAS-28: 3.77 vs. 2.72, respectively [$p=0.009$]). ACPA positivity was observed in 15.9% of patients with PsA and in 0.0% of patients with psoriasis ($p=0.04$). Among 44 of the 52 patients with PsA whose ACPA data were available, the duration from skin onset to joint onset was shorter in the 7 ACPA-positive patients (54.3±52.8 months) than in the 37 ACPA-negative patients (147.8±158.0 months), although the difference was not statistically significant ($p=0.30$). There were no statistically significant differences in the PASE, DAS-28, C-reactive protein concentration, or matrix metalloproteinase-3 concentration. The differences between RF positive and negative patients were not also statistically significant.

Table 1

	ACPA Positive (n=7)	ACPA Negative (n=37)	p value
PASE	45.8±16.1	51.1±13.4	0.42
IBP positivity	28.6	40.5	0.69
DAS28-ESR	4.24±0.93	3.76±1.56	0.45
DAS28-CRP	3.78±0.73	3.67±1.39	0.84
CRP (mg/dl)	0.56 [0.02–20.39]	0.48 [0.00–16.05]	0.79
MMP-3 (ng/ml)	133.6 [42.8–184.2]	69.1 [13.5–245.1]	0.14
Duration (skin/SpA) (mo)	54.3±52.8	147.8±158.0	0.26

Data are presented as mean ± standard deviation or median [range] unless otherwise indicated.

Conclusions: Among the patients with PsA in this series, ACPA positivity occurred in 15.9% and RF positivity occurred in 12.8%. Seropositive patients with PsA tended to have a shorter duration between skin onset and joint onset. Clinical and laboratory findings were not significantly different between ACPA-positive and -negative patients. One possible explanation for this is that 40.4% of patients with PsA received biological disease-modifying antirheumatic drugs; therefore, their disease activity was stable.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.1898

AB0769 SONOGRAPHIC SIGNS OF ENTHESITIS IN ESTABLISHED PSORIATIC ARTHRITIS AND HEALTHY VOLUNTEERS

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Background: Previous research in our group showed that sonographic signs of enthesitis are present in early and established PsA, but in young healthy volunteers as well. The Madrid Sonographic Enthesitis Index (MASEI) was only able to differentiate between patients and healthy volunteers after excluding knee enthesitis thickness from the score and semi-quantitative scoring of Power Doppler (PD) signal (1).

Objectives: We aim to validate the modified MASEI in a larger cohort of established PsA patients and healthy volunteers.

Methods: Established PsA patients and healthy volunteers aged 35–55 were asked to participate in this cross-sectional study, irrespective of presence of enthesitis complaints. The triceps, quadriceps, proximal and distal patellar and Achilles tendon and plantar fascia (i.e. the locations of the MASEI) and the common extensor insertion at the lateral epicondyle of the elbow were evaluated sonographically for structural changes (i.e. erosions, calcifications and structure) and active inflammation (thickness, bursitis and PD).

Results: 84 established PsA patients and 25 healthy volunteers participated. Sonographic structural changes and one or two spots of PD signal were common in both groups. The modified MASEI was significantly higher in PsA patients