Table. Analysis of Categorical RAPID-3 by DAPSA and MDA Categories at Week 24.

Disease Activity Assessment		RAPID-3				Kappa
		Remission ≤3	LowDA >3 – ≤6	ModDA >6 – ≤12	HighDA >12	
DAPSA						
Adalimumab	Remission	29 (20.9)	3 (2.2)	1 (0.7)	0	0.388 ^a 0.572 ^b
	LowDA	15 (10.8)	11 (7.9)	6 (4.3)	1 (0.7)	
	ModDA	6 (4.3)	8 (5.8)	17 (12.2)	4 (2.9)	
	HighDA	4 (2.9)	4 (2.9)	12 (8.6)	18 (12.9)	
Placebo	Remission	4 (2.8)	0	0	0	0.284 ^d 0.484 ^b
	LowDA	5 (3.4)	3 (2.1)	5 (3.4)	1 (0.7)	
	ModDA	1 (0.7)	7 (4.8)	16 (11)	9 (6.2)	
	HighDA	1 (0.7)	4 (2.8)	29 (20)	60 (41.4)	
Minimal Disease Activity						
Adalimumab	MDA					0.574 ^c 0.252 ^c
	Yes	45 (32.1)	5 (3.6)	1 (0.7)	0	
	No	9 (6.4)	21 (15)	36 (25.7)	23 (16.4)	
	V LDA					
Placebo	MDA					0.392 ^c 0.119 ^d
	Yes	7 (4.8)	0	0	0	
	No	4 (2.8)	14 (9.7)	50 (34.5)	70 (48.3)	
	V LDA					
Adalimumab	Yes	1 (1.4)	0	0	0	0.119 ^d
	No	7 (10.1)	5 (7.2)	17 (24.6)	39 (56.5)	

All values are n (%), unless otherwise indicated.

^aKappa agreement between the numbers of patients across the disease activity categories of the RAPID-3 and the DAPSA.^bKappa agreement between the numbers of patients in the remission + LowDA and ModDA + HighDA disease activity categories of the RAPID-3 and the DAPSA.^cKappa agreement between the numbers of patients in the remission + LowDA and ModDA + HighDA disease activity categories of the RAPID-3 and achievement (yes/no) of 5 (MDA) or 7 of 7 (V LDA) criteria of minimal disease activity.

DAPSA disease activity states: remission, ≤4; LowDA, ≤14; ModDA, ≤28; HighDA, >28. Minimal disease activity criteria: TJC ≤1, SJC ≤1, PASI ≤1, patient Pain ≤15, patient global ≤20, HAQ-DI ≤0.5; tender entheseal points ≤1.

RAPID-3, routine assessment of patient index data; DAPSA, disease activity index in psoriatic arthritis; MDA, minimal disease activity; LowDA, low disease activity; ModDA, moderate disease activity; HighDA, high disease activity; V LDA, very low disease activity.

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FRI0511 SECUKINUMAB DEMONSTRATES CONSISTENT SAFETY OVER LONG-TERM EXPOSURE 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 psoriasis (PsO) and psoriatic arthritis (PsA) clinical trial programs after ~1 year of exposure have been reported.^{1,2}

Objectives: To report updated longer-term secukinumab exposure safety data from PsO and PsA studies (data cut-off: 25 June 2016).

Methods: The PsO data pool consisted of 9 Phase III studies in moderate-to-severe plaque PsO and PsA pool consisted of 3 Phase III studies in active PsA. Secukinumab doses differed in the studies and 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 secukinumab at 12–24 weeks depending on study design. Only data for approved secukinumab 300 and 150mg doses were included in analysis. Exposure adjusted incident rates (EAIR) were used to adjust for differences in exposure.

Results: In both PsO and PsA, the most frequently reported adverse events (AEs) with secukinumab were non-serious infections of the upper respiratory tract, headache and arthralgia (Table). The EAIRs of AEs of special interest with secukinumab including Crohn's disease, *Candida* infections, serious infections, inflammatory bowel disease, major adverse cardiac events and neutropenia (reported in the Table) were similar in both PsO and PsA indications, and comparable to those reported previously.^{1,2} No cases of tuberculosis (new onset or reactivation) were reported.

Table 1. Summary of pooled safety of secukinumab in PsO and PsA

	PSO Any secukinumab N=3893	PsA Any secukinumab N=1128
Total exposure, patient-years)	7769.0	1907.0
Min-max exposure (days)	1–1526	16–1464
Death, n (%)	7 (0.2)	4 (0.4)
AE's by EAIR: AE per 100 Pt-years (95% CI)		
Any AE	196.9 (190.3, 203.6)	173.7 (162.5, 185.5)
Any serious AE	7.2 (6.6, 7.8)	8.5 (7.2, 10.0)
Frequent AEs ¹		
Nasopharyngitis	18.2 (17.1, 19.3)	13.7 (12.0, 15.7)
Headache	6.3 (5.7, 6.9)	4.8 (3.9, 5.9)
Upper respiratory tract infections	6.2 (5.6, 6.8)	11.2 (9.6, 12.9)
Arthralgia	5.1 (4.6, 5.6)	4.3 (3.4, 5.3)
AEs of special interest		
<i>Candida</i> infections	2.1 (1.8, 2.4)	2.3 (1.6, 3.1)
Serious infections	1.4 (1.2, 1.7)	1.8 (1.3, 2.5)
Inflammatory Bowel Disease	0.3 (0.2, 0.4)	0.5 (0.2, 0.9)
Crohn's disease	0.1 (0.0, 0.1)	0
Ulcerative colitis	0.2 (0.1, 0.3)	0.1 (0.0, 0.4)
MACE	0.3 (0.2, 0.5)	0.3 (0.1, 0.6)
Neutropenia	0.4 (0.3, 0.5)	0.7 (0.4, 1.2)

¹ Adverse events in the secukinumab group that occurred with an IR >5.0 during the entire safety period in either of the pooled groups; AE, adverse event; EAIR, exposure adjusted incidence rate per 100 patient-years; MACE, major adverse cardiac event; N, number of patients in the analysis.

Conclusions: The safety profile of secukinumab was similar for PsO and PsA patients supporting its long-term use in these chronic conditions. Secukinumab long-term exposure safety data is consistent with that previously reported with shorter-term exposure, including being well tolerated, and without any new safety signals identified.

References:

[1] Van de Kerkhof PC, et al. J Am Acad Dermatol 2016;75:83–98.

[2] Mease PJ, et al. Arthritis Rheumatol 2015; 67:A2886.

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FRI0512 APREMILAST, AN ORAL PHOSPHODIESTERASE 4 INHIBITOR, IS ASSOCIATED WITH LONG-TERM (156-WEEK) IMPROVEMENTS IN BASDAI IN PSORIATIC ARTHRITIS PATIENTS: POOLED RESULTS FROM 3 PHASE III, RANDOMIZED, CONTROLLED TRIALS

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Background: In PALACE psoriatic arthritis (PsA) studies, the Bath Ankylosing Spondylitis Disease Activity Index score (BASDAI) was used as an exploratory measure in a subset of patients (pts) considered by investigators to have axial involvement, although PsA spondylitis was not confirmed by imaging.

Objectives: Report the impact of apremilast 30 mg BID (APR) treatment on BASDAI over 156 wks using pooled PALACE 1–3 data of pts with active PsA despite prior conventional DMARDs and/or biologics.