Abstract AB0944 – Table 1. SPIRIT-P2 outcomes and safety results at 24 weeks according to cDMARD use at baseline.

Outcomes	Background cDMARD			Background MTX			Monotherapy		
	PBO n=52	IXEQ4W n=60	IXEQ2W n=73	PBO n=40	IXEQ4W n=48	IXEQ2W n=61	PBO n=66	IXEQ4W n=62	IXEQ2W n=50
ACR20, n (%)	12 (23.1)	30 (50.0)*	34 (46.6)*	7 (17.5)	24 (50.0)*	31 (50.8)*	11 (16.7)	35 (56.5)*	25 (50.0)*
ACR50, n (%)	4 (7.7)	17 (28.3)*	22 (30.1)*	3 (7.5)	15 (31.3)*	20 (32.8)*	2 (3.0)	26 (41.9)*	19 (38.0)*
MDA*, n (%)	1 (1.9)	18 (30.0)*	14 (19.2)*	0	15 (31.3)*	13 (21.3)*	3 (4.5)	16 (25.8)*	15 (30.0)*
DAS28-CRP, LSM (SE)	-0.6 (0.17)	-1.8 (0.16)*	-1.2 (0.14)*	-0.5 (0.21)	-1.9 (0.19)*	-1.2 (0.16)*	-0.4 (0.17)	-1.7 (0.17)*	-1.8 (0.19)*
DAS28, LSM (SE)	-11.5 (2.8)	-25.4 (2.7)*	-19.0 (2.4)*	-9.2 (3.4)	-24.7 (3.1)*	-18.2 (2.7)*	-6.4 (2.8)	-26.0 (2.8)*	-26.9 (3.2)*
HAQ-DI, LSM (SE)	0.0 (0.07)	-0.3 (0.06)*	-0.2 (0.06)	0 (0.01)	-0.3 (0.01)*	-0.2 (0.01)	0.0 (0.06)	-0.5 (0.06)*	-0.4 (0.07)*
HAQ-DI MCID†, n (%)	9 (17.3)	17 (28.3)	20 (27.4)	7 (19.4)	14 (35.9)	17 (32.1)	9 (13.6)	28 (45.2)*	23 (46.0)*
Safety									
TEAE (≥1), n (%)	33 (63.5)	43 (71.7)	51 (69.9)	25 (62.5)	35 (72.9)	40 (65.6)	43 (65.2)	40 (64.5)	39 (78.0)
Serious AEs, n (%)	2 (3.8)	1 (1.7)	4 (5.5)	2 (5.0)	1 (2.1)	3 (4.9)	2 (3.0)	2 (3.2)	4 (8.0)
Serious Infections‡	0	0	2 (2.7)	0	0	2 (3.3)	0	0	1 (2.0)
Discontinuation due to AE, n (%)	4 (7.7)	3 (5.0)	3 (4.1)	4 (10.0)	1 (2.1)	3 (4.9)	2 (3.0)	2 (3.2)	5 (10.0)

*Patients classified as achieving MDA if they fulfilled 5 of 7 MDA criteria.

†HAQ-DI (Health Assessment Questionnaire-Disability Index) minimal clinically important difference (MCID) defined as improvement ≥ 0.35 in patients with a baseline HAQ-DI ≥ 0.35

‡None of the reported serious infections were related to *Candida* or *Tuberculosis*
* $p < 0.05$, † $p < 0.01$, ‡ $p < 0.001$, all versus placebo; ACR, American College of Rheumatology; LSM, least squares mean; n, number of patients; SE, standard error

Conclusions: The efficacy of IXE versus PBO in PsA was similar in patients with or without background cDMARD use in this post hoc analysis with safety profiles comparable to the overall trial population.³

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3

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AB0945

SECUKINUMAB EFFICACY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: POOLED ANALYSIS OF FOUR PHASE 3 TRIALS BY PRIOR ANTI-TNF THERAPY AND CONCOMITANT METHOTREXATE USE

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Background: Secukinumab has demonstrated rapid, significant and sustained improvement in the signs and symptoms of psoriatic arthritis (PsA) in multiple Phase 3 studies.¹⁻³

Objectives: To report pooled efficacy results for secukinumab versus placebo at Week (Wk) 16 in PsA patients (pts) by previous anti-TNF therapy and with or without concomitant methotrexate (MTX) use from four Phase 3 studies: FUTURE 2, FUTURE 3, FUTURE 4 and FUTURE 5.

Methods: Overall, 397, 414, 341, and 996 pts with active PsA were randomised in FUTURE 2, FUTURE 3, FUTURE 4 and FUTURE 5, respectively. Secukinumab doses included subcutaneous (s.c.) 300 mg and 150 mg administered at

baseline (BL) with loading doses at Wks 1, 2, and 3, followed by maintenance dose every 4 wks (q4w) starting at Wk 4 and s.c. secukinumab 150 mg administered at BL without loading dose, followed by q4w starting at Wk 4. Data collected up to Wk 16 were pooled. Assessments included ACR20/50/70, DAS-28 CRP, PASI 75/90, SF-36 PCS, HAQ-DI, and resolution of dactylitis, and enthesitis. Pooled analyses examined the effect of prior anti-TNF use (naïve/inadequate response or intolerance to these agents, -IR) and with/without MTX use on clinical endpoints and are reported after application of non-responder imputation for binary variables and a mixed-effects model for repeated measures for continuous variables.

Results: A total of 2049 pts were included in the analysis, of which 461, 572, 335, and 681 pts received secukinumab 300 mg, 150 mg, 150 mg without load and placebo, respectively. Improvements were observed with secukinumab vs placebo for all endpoints at Wk 16 in both anti-TNF-naïve and anti-TNF-IR pts and in pts with and without concomitant MTX use. Higher ACR and PASI responses and greater improvement of disease activity were observed in anti-TNF-naïve pts compared to anti-TNF-IR pts. Secukinumab 300 mg provided numerically higher ACR and PASI responses compared to the 150 mg dose particularly for anti-TNF-IR pts and in pts with no concomitant MTX use. Earlier responses were observed with secukinumab with load compared to without load primarily across ACR, DAS28-CRP and PASI endpoints.

Abstract AB0945 – Figure 1

Conclusions: Secukinumab provided improvements in the signs and symptoms of active PsA regardless of previous anti-TNF therapy or concomitant MTX use. Higher response rates were generally observed in anti-TNF-naïve pts compared to anti-TNF-IR pts. Secukinumab 300 mg was associated with higher responses compared to 150 mg particularly in anti-TNF-IR pts and in pts with no concomitant MTX use.

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AB0946 IMPROVEMENTS IN WORK PRODUCTIVITY WITH UP TO 104 WEEKS OF APREMILAST MONOTHERAPY: RESULTS FROM A PHASE 3B, RANDOMISED, CONTROLLED STUDY IN BIOLOGIC-NAÏVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) patients may experience disease manifestations across multiple domains and impaired functioning in daily activities at home and work. The phase 3b ACTIVE study is evaluating the efficacy of apremilast (APR) monotherapy in biologic-naïve subjects with active PsA who may have had exposure to 1 prior conventional DMARD.

Objectives: To assess work productivity through Week 104.

Methods: Subjects were randomised (1:1) to receive APR 30 mg BID or placebo (PBO). Subjects who did not improve by $\geq 10\%$ in swollen and tender joint counts at Week 16 were eligible for early escape. At Week 24, all remaining PBO subjects were switched to APR. Work productivity and activity impairment were assessed at baseline (BL) and Week 16 using the 6-item, self-administered Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis (WPAI:PsA). WPAI:PsA includes 4 subscale scores (Absenteeism, Presenteeism, Work Productivity Loss, and Activity Impairment), each ranging from 0% to 100%; higher scores indicate greater impairment. Work-related subscales were evaluated only among employed subjects, while activity impairment was evaluated among all subjects, regardless of employment. Correlations were examined at Week 16 between WPAI:PsA subscale scores and the SF-36v2 domain scores for Physical Functioning (PF), Bodily Pain (Pain), and Vitality (VIT), as well as associations with ACR20 response. Improvement in work productivity was assessed through Week 104.

Results: BL characteristics were similar between APR and PBO subjects with WPAI:PsA scores included in this analysis. At Week 16, APR significantly improved work productivity and the ability to carry out daily activities vs PBO, with significantly greater mean improvements observed in the overall Work Productivity Loss ($p=0.001$) and Activity Impairment ($p<0.001$) scores (table 1). Estimated mean change in the Absenteeism score was similar with APR vs PBO ($p=0.679$). By contrast, the Presenteeism score showed significant improvement with APR vs worsening with PBO (-10.8% vs 4.1% ; $p=0.002$). At Week 16, statistically significant correlations were observed between WPAI:PsA subscale scores (except Absenteeism) and the SF-36v2 domain scores for PF, Pain, and VIT, as were associations with ACR20 response. Among subjects randomised to APR at BL, improvements in Week 16 WPAI:PsA subscale score were generally maintained through Week 104 in those continuing APR.

Improvements in WPAI:PsA Subscale Scores (% Point) at Week 16				
WPAI:PsA Subscale	APR 30 mg BID LS Mean (95% CI) n=39	PBO LS Mean (95% CI) n=56	Treatment Difference (95% CI)	P Value
Presenteeism	-10.8 (-17.8, -3.8)	4.1 (-1.7, 9.9)	-14.9 (-24.1, -5.8)	0.002
Work Productivity Loss	-11.9 (-18.8, -5.0)	3.5 (-2.4, 9.4)	-15.4 (-24.5, -6.2)	0.001
Activity Impairment	-11.8 (-16.4, -7.1)	-0.5 (-4.7, 3.8)	-11.3 (-17.6, -5.0)	<0.001
Absenteeism	-3.6 (-5.9, -1.3)	-3.0 (-4.9, -1.0)	-0.6 (-3.7, 2.4)	0.679

Abstract AB0946 – Figure 1

Results are from an analysis of covariance model, adjusted with BL WPAI: PsA subscale score, BL prednisone use (yes/no), and previous DMARD use (yes/no). LS mean is estimated using the observed margins of the covariates. WPAI: PsA scores were evaluated for subjects with values at both BL and Week 16. Absenteeism, Presenteeism, and Work Productivity Loss were evaluated only among employed subjects. Activity Impairment scores were evaluated among all randomised subjects with scores at BL and Week 16, regardless of employment status. CI=confidence interval; LS=least square.

Conclusions: In biologic-naïve subjects with PsA, APR monotherapy contributed to an overall improvement in work productivity at Week 16, which correlated with SF-36v2 PF, Pain, and VIT scores and was associated with ACR20 response; improvements in WPAI:PsA subscale scores were generally maintained to Week 104.

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AB0947 IMPACT OF CLINICAL SPECIALTY SETTING ON DISEASE MANAGEMENT IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS FROM A CROSS-SECTIONAL OBSERVATIONAL STUDY IN THE UNITED STATES

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Background: Early diagnosis and effective treatment has been shown to decrease functional disability and structural progression in patients (pts) with psoriatic arthritis (PsA).¹ However, factors that influence treatment management decisions are poorly understood.

Objectives: To evaluate the impact of clinical specialty setting on the management of US pts with PsA.

Methods: LOOP was a multi-centre, cross-sectional observational study conducted across 44 sites in US. Adult pts with a suspected or an established diagnosis of PsA who were routinely visiting a rheumatologist (rheum) or a dermatologist (derm) were eligible to participate in this study. Each enrolled pt was assessed by both rheum and derm. The association between enrolling or diagnosing clinical specialty setting and time from symptom onset to PsA diagnosis and to different disease management steps were examined.

Abstract AB0947 – Table 1. Current Disease Activity and Disease Burden by Clinical Specialty in US Patients with PsA from LOOP Study

Measure ^a	Rheum (N=366)	Derm (N=147)	P-value [*]
TJC68	8.2 (10.8)	9.9 (10.3)	.095
SJC66	3.4 (6.4)	4.3 (6.0)	.154
DAS28 (CRP)	3.2 (1.5) ^b	4.2 (2.0) ^c	.095
DAS28 (ESR)	3.1 (1.6) ^d	3.8 (2.1) ^e	.192
Enthesitis based on LEI	1.0 (1.6)	1.5 (1.8)	.005
Dactylitis count	0.6 (1.5)	0.8 (1.7)	.241
BASDAI (axial involvement)	4.6 (3.2) ^f	4.3 (3.3) ^g	.248
BSA (%)	5.0 (10.9)	8.1 (14.5)	.024
Psoriatic nail count	1.9 (3.1) ^h	2.0 (3.1)	.734
PASI	3.0 (5.1)	5.5 (7.9)	<.001
PtGA at the time of diagnosis	6.7 (2.7) ^k	5.9 (3.1) ^l	.003
PtGA during last visit	4.7 (2.9) ^m	4.7 (3.0) ⁿ	.976
HAQ-DI	0.9 (0.7)	0.7 (0.7)	.057
SF1v2 PCS	40.6 (10.5) ^o	41.8 (10.3)	.244
SF12v2 MCS	46.9 (11.1) ^p	47.9 (11.9)	.361
DLQI	5.4 (5.9) ^q	7.8 (7.4)	.001

^{*}P-value from two sample t-test: Rheumatologist vs Dermatologist.

^aAll data are presented as mean (SD) unless otherwise specified.

^bN=40; ^cN=8; ^dN=67; ^eN=13; ^fN=361; ^gN=144; ^hN=321; ⁱN=314; ^jN=145; ^kN=365; ^lN=138; ^mN=341; ⁿN=65; ^oN=361.

BSA=body surface area with psoriasis; DAS28 (CRP)=28 joint disease activity score based on C-reactive protein; DAS28 (ESR)=DAS28 based on erythrocyte sedimentation rate; Derm=dermatologist; DLQI=Dermatology life quality index; HAQ-DI=health assessment questionnaire – disability index; LEI=Leeds enthesitis index; MCS=mental component score; PASI=psoriasis area and severity index; PCS=physical component score; PGA=physician global assessment; PsA=psoriatic arthritis; PtGA=patient's global assessment of disease; Rheum=rheumatologist; SF12v2=Short form 12-item health survey version 2.0; SD=standard deviation; SJC66=swollen joint count, 66 joints; TJC68=tender joint count, 68 joints.