Conclusions: A substantial portion of patients with moderate to severe chronic plaque psoriasis who were partial or nonresponders to ETN may respond after switching to treatment with TIL 200 mg. TIL may be a reasonable option for those who do not achieve adequate response to ETN.

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Acknowledgements: This study was funded by Merck and Co., Inc. Editorial support for abstract submission was provided by Fishawack Communications and funded by Sun Pharmaceutical Industries, Inc. Analyses were presented at the American Academy of Dermatology Annual Meeting, San Diego, California, USA, 2018

Disclosure of Interest: J. Crowley Grant/research support from: Abbvie, Amgen, Sun Pharma, Lilly, Novartis, Janssen, Regeneron, Sanofi, Merck, Pfizer, Sandoz, MC2 Therapeutics, Verrica, Consultant for: Abbvie, Sun Pharma, Dermira, Lilly, Novartis, Celgene, Speakers bureau: Abbvie, Lilly, Novartis, Regeneron, Sanofi, K. Papp Grant/research support from: Abbvie, Akros, Amgen, Anacor, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, EMD Serono, Janssen, Kyowa Hakko Kirin, Meiji Seika Pharma, Merck SharpDome, Mitsubishi Pharma, Novartis, Pfizer, UCB, Valeant, Consultant for: Abbvie, Akros, Amgen, Anacor, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, EMD Serono, Janssen, Kyowa Hakko Kirin, Meiji Seika Pharma, Merck SharpDome, Mitsubishi Pharma, Novartis, Pfizer, UCB, Valeant, Speakers bureau: Abbvie, Amgen, Celgene, Eli Lilly, Janssen, Kyowa Hakko Kirin, Novartis, Pfizer, UCB, Valeant, C.-H. Hong Grant/research support from: Amgen, Abbvie, Eli Lilly, Janssen, Merck, Novartis, GlaxoSmithKline, Celgene, UCB, Consultant for: Amgen, Abbvie, Eli Lilly, Janssen, Novartis, GlaxoSmithKline, Celgene, Sun Pharma, Speakers bureau: Amgen, Abbvie, Eli Lilly, Janssen, Novartis, Celgene, J. Parno Employee of: Sun Pharmaceutical Industries, Inc., A. Mendelsohn Employee of: Sun Pharmaceutical Industries, Inc., Q. Li Employee of: Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., Kenilworth, NJ, USA, N. Cichanowitz Shareholder of: Merck and Co., Inc., Employee of: Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., Kenilworth, NJ, USA, C. La Rosa Employee of: Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., Kenilworth, NJ, USA
DOI: 10.1136/annrheumdis-2018-eular.6758

AB0904 CORRELATION OF RAPID3 AND PROMIS10 IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: In addition to clinician assessment and laboratory tests, patient-reported outcomes (PROs) are important for managing and improving the quality of care in patients with psoriatic arthritis (PsA). The RAPID3 was originally developed for use in patients with rheumatoid arthritis, but it may be used in clinical practice to assess disease activity in patients with PsA.¹ The PROMIS10 is a general (nondisease-specific) PRO instrument that measures physical, mental, and social health.² Developed for the general population, PROMIS10 has not yet been specifically validated in PsA.

Objectives: To evaluate the relationship between RAPID3 and PROMIS10 in patients with PsA.

Methods: US adults with a self-reported diagnosis of PsA were recruited through CreakyJoints (www.CreakyJoints.org), an online patient support community comprising patients with arthritis and arthritis-related diseases and their caregivers. Respondents completed an online survey that was designed to collect data on socio-demographics and clinical symptoms and included the RAPID3 and PROMIS10 to evaluate disease activity and health-related quality of life (HRQoL), respectively. The RAPID3 consists of three patient self-reported scores (0–10): functional impairment, pain, and patient global assessment; total score ≤ 3.0 = near remission, 3.1 to 6.0 = low disease severity, 6.1 to 12.0 = moderate disease severity, and ≥ 12.1 = high disease severity. PROMIS10 is a 10-item survey measuring physical and mental domains; individual scores are transformed to T-score distributions normalised to the general population. PROMIS10 individual scores and global physical and mental health T-scores were stratified by RAPID3 disease severity and compared across RAPID3 severity levels using Kruskal-Wallis or ANOVA tests, respectively. Spearman's correlation coefficient was calculated between RAPID3 total score and the PROMIS10 physical health and mental health T-scores, respectively.

Results: Among 203 respondents, the mean (SD) age was 51.6 (10.8) years and 172 (84.7%) were female. The mean (SD) cumulative RAPID3 score was 14.7 (5.8) with mean (SD) functional impairment, pain tolerance, and patient's global estimate scores of 3.3 (1.8), 6.0 (2.3), and 5.4 (2.5), respectively. Patients' mean (SD) PROMIS10 global physical and mental health T-scores were 36.4 (7.3) and

40.2 (9.3), respectively. The mean individual domain scores and global T-scores worsened with increasing RAPID3 disease severity levels (all $p < 0.001$) (table 1). PROMIS10 physical and mental health T-scores showed a strong ($r_s = -0.84$) and moderate correlation ($r_s = -0.57$) with RAPID3, respectively.

Abstract AB0904 – Table 1. PROMIS10 Scores and Impact of PsA on Work by RAPID3 Disease Activity in Patients with PsA

	RAPID3 Disease Activity*				P value
	Near Remission	Low Severity	Moderate Severity	High Severity	
PROMIS10 domain, mean (SD)	n = 5	n = 14	n = 45	n = 139	
Overall health	3.60 (0.55)	2.93 (0.73)	2.87 (0.69)	2.10 (0.73)	< 0.0001
Quality-of-life	4.20 (0.84)	3.07 (0.83)	3.16 (0.74)	2.29 (0.89)	< 0.0001
Physical health	3.60 (0.55)	2.79 (0.89)	2.73 (0.62)	1.97 (0.73)	< 0.0001
Mental health	4.40 (0.55)	3.14 (1.10)	3.11 (1.05)	2.63 (1.10)	0.0004
Satisfaction with social activities/relationships	4.20 (0.45)	3.00 (0.96)	3.09 (1.06)	2.06 (1.09)	< 0.0001
Ability to carry out every day physical activities	4.80 (0.45)	4.36 (0.63)	3.80 (0.73)	2.68 (0.76)	< 0.0001
Emotional distress	4.80 (0.45)	3.43 (1.16)	3.16 (0.80)	2.65 (1.00)	< 0.0001
Fatigue	4.00 (1.00)	3.50 (0.65)	3.04 (0.71)	2.25 (0.76)	< 0.0001
Pain	4.20 (0.45)	3.93 (0.27)	3.38 (0.49)	2.40 (0.56)	< 0.0001
Global physical health T-score	52.84 (3.07)	46.66 (3.69)	42.35 (4.54)	32.91 (5.06)	< 0.0001
Global mental health T-score	58.44 (5.86)	45.17 (7.60)	44.84 (7.53)	37.50 (8.56)	< 0.0001

PROMIS10, Patient-Reported Outcome Management Information System Global Health short form; RAPID3, Routine Assessment of Patient Index Data 3.

* Disease severity classified by RAPID3 scores: ≤ 3.0 = near remission; 3.1 to 6.0 = low severity; 6.1 to 12.0 = moderate severity; ≥ 12.1 = high severity.

Conclusions: RAPID3 and PROMIS10 physical health T-scores were strongly correlated in patients with PsA. PROMIS10 mental health scores moderately correlated with RAPID3, suggesting the mental health questions add a different construct. PROMIS10 and RAPID3 are relatively short questionnaires that can be used in the real world to track and monitor disease symptoms and HRQoL in patients with PsA.

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Acknowledgements: This study was sponsored by Novartis Pharmaceuticals Corporation, East Hanover, NJ.

Disclosure of Interest: A. Ogdie Grant/research support from: Pfizer and Novartis, Consultant for: Abbvie, BMS, Eli Lilly and Company, Novartis, Takeda, and Pfizer, W. B. Nowell Employee of: Global Healthy Living Foundation, E. Applegate: None declared, K. Gavigan Employee of: Global Healthy Living Foundation, S. Venkatachalam Employee of: Global Healthy Living Foundation, M. de la Cruz Employee of: ICON, E. Flood Employee of: ICON, E. Schwartz Employee of: ICON, B. Romero Employee of: ICON, P. Hur Employee of: Novartis Pharmaceuticals Corporation

DOI: 10.1136/annrheumdis-2018-eular.5048

AB0905 LONG-TERM (5-YEAR) EFFICACY AND SAFETY OF APREMILAST MONOTHERAPY IN DMARD-NAÏVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Apremilast (APR) is an oral phosphodiesterase 4 inhibitor that helps regulate the immune responses that cause joint inflammation and other manifestations of psoriatic arthritis (PsA), including skin disease.

Objectives: To describe the long-term (5 year) efficacy and safety of APR monotherapy in DMARD-naïve subjects with active PsA from the phase 3 PALACE 4 study.

Methods: Subjects were randomised (1:1:1) to receive placebo, APR 30 mg BID (APR30), or APR 20 mg BID (APR20). At Week 16, subjects were eligible for early escape; placebo subjects were re-randomised to APR treatment, and APR subjects remained on their assigned dose. At Week 24, all subjects remaining on placebo were re-randomised to APR. Double-blind treatment continued to Week 52, with open-label APR treatment for up to 4 additional years.

Results: A total of 527 subjects were randomised and received ≥ 1 dose of placebo (n=176), APR30 (n=176), or APR20 (n=175). Among subjects randomised to APR30 at baseline, 45.5% (80/176) completed the Week 260 visit. At Week 52, modified ACR20, ACR50, and ACR70 responses were achieved by 58.0%, 29.8%, and 15.5% of subjects receiving APR30, respectively, regardless of when APR was started (baseline, Week 16, or Week 24). Rates of improvement in PsA signs and symptoms and physical function were sustained up to Week 260 with continued APR30 treatment, including reduction rates in SJC of 84.8% and in TJC of 76.4% (table 1). At Week 260, 65.8%, 39.0%, and 20.3% of subjects achieved a modified ACR20, ACR50, and ACR70 response, respectively, and 71.2% of APR30 subjects with baseline enthesitis achieved a MASES of 0; 95.1% with baseline dactylitis achieved a dactylitis count of 0. At Week 260, 52.9% of subjects achieved a HAQ-DI MCID ≥ 0.35 , 60.3% achieved a PASI-50 response, and 47.6% achieved a PASI-75 response (table 1). No new safety concerns were identified with APR up to 260 weeks. During Weeks>208 to $\leq$ 260, the most common adverse event (AEs) among APR30-exposed subjects was nasopharyngitis (6.9%). Serious AEs occurred in 5 APR30 subjects; serious infections were reported in 2 APR30 subjects (pelvic abscess and bacterial urinary tract infection), and no opportunistic infections were reported during Weeks>208 to $\leq$ 260.

Abstract AB0905 – Table 1

	Outcomes at Week 260
	APR30 n=119*
ACR20, n/m [§] (%)	77/117 (65.8)
ACR50, n/m [§] (%)	46/118 (39.0)
ACR70, n/m [§] (%)	24/118 (20.3)
SJC, mean % change	-84.8
TJC, mean % change	-76.4
MASES of 0, n/m (%) [‡]	47/66 (71.2)
Dactylitis count of 0, n/m (%) [‡]	58/61 (95.1)
HAQ-DI (0-3), mean change	-0.38
HAQ-DI MCID $\geq 0.35^{\dagger}$, n/m (%)	63/119 (52.9)
PASI-50, n/m (%) [¶]	38/63 (60.3)
PASI-75, n/m (%) [¶]	30/63 (47.6)

Conclusions: APR monotherapy demonstrated sustained response or improvements in PsA signs and symptoms, including SJC and TJC, enthesitis, dactylitis, physical function, and psoriasis in the population of subjects continuing treatment over 260 weeks. APR continued to demonstrate a favourable safety profile and was generally well tolerated.

Disclosure of Interest: A. Wells Grant/research support from: Celgene Corporation, C. Edwards Grant/research support from: Celgene Corporation; Pfizer, Roche, Samsung, Consultant for: Celgene Corporation, Pfizer, Roche, Samsung, Speakers bureau: Abbott, GSK, Pfizer, Roche, A. Kivitz Consultant for: Celgene Corporation, Speakers bureau: Celgene Corporation, P. Bird Grant/research support from: Celgene Corporation, B. Guerette Employee of: Celgene Corporation, N. Delev Employee of: Celgene Corporation, M. Paris Employee of: Celgene Corporation, L. Teng Employee of: Celgene Corporation, J. Aelion Grant/research support from: Celgene Corporation; AbbVie, Ardea Biosciences, AstraZeneca, BMS, Centocor, Eli Lilly, Galápagos, Genentech, GSK, Human Genome Sciences, Janssen, Merck, Mesoblast, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi-Aventis, Takeda Pharmaceuticals, UCB, Vertex Pharmaceuticals

DOI: 10.1136/annrheumdis-2018-eular.3113

AB0906 IXEKIZUMAB IMPROVES FATIGUE IN A SUBSET OF PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) is a chronic, systemic, inflammatory disease with both articular and extra-articular symptoms including joint pain, enthesitis, dactylitis, and fatigue. Fatigue is increasingly recognised as a priority symptom to patients and has been added to the PsA core set of outcomes for clinical trials.¹ The best instrument to assess fatigue has not yet been defined.

Objectives: To assess fatigue improvement following treatment with ixekizumab (IXE), an anti-interleukin (IL)-17A monoclonal antibody, relative to placebo (PBO) in PsA patients.

Methods: In two phase 3 randomised controlled trials, patients naïve to and experienced with biologic disease-modifying antirheumatic drugs (SPIRIT-P1, SPIRIT-P2, respectively) received subcutaneous PBO, ADA 40 mg every 2 weeks (SPIRIT-P1 only; reference arm), or IXE 80 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) after a 160 mg starting dose for up to 24 weeks. At Week 16, all patients considered inadequate responders (IR) received rescue therapy. PBO and ADA patients were re-randomised (1:1) to Q2W or Q4W at Week 16 (IR) or Week 24; ADA patients underwent a washout prior to IXE treatment. Patients rated their worst level of fatigue during the past 24 hours at baseline, Week 4, 12, 16, 24, 32, and 52 on the 11-point Fatigue Severity Numeric Rating Scale (Fatigue NRS; not yet validated) where 0=no fatigue and 10=as bad as you can imagine. The minimal clinically important difference (MCID) was defined as an improvement ≥ 3 on the Fatigue NRS.

Results: At Week 24 significantly more patients in both studies achieved fatigue improvements ≥ 3 on the Fatigue NRS with both IXE doses versus PBO (table 1; NRI). When evaluating group level changes, statistically significant improvements on the Fatigue NRS were observed with both IXE doses versus PBO prior to Week 24 in both studies. At Week 24, significance was observed in the SPIRIT-P2 study only (table 1; MMRM). For patients who continued IXE treatment beyond Week 24, mean improvements on the Fatigue NRS persisted through Week 52 (table 1; MI).

Table 1

	SPIRIT-P1				SPIRIT-P2		
	PBO n=106	ADA n=101	Q4W n=107	Q2W n=103	PBO n=118	Q4W n=122	Q2W n=123
Baseline fatigue mean (SD)	5.37 (2.22)	5.45 (2.34)	5.76 (2.29)	5.52 (2.44)	5.9 (2.28)	5.9 (2.48)	6.0 (2.49)
Change from baseline at Week 24 ^a	-1.3 (0.25)	-1.5 (0.24)	-1.6 (0.24)	-1.9 (0.24)	-0.7 (0.37)	-2.0 (0.35)	-2.1 (0.34)
LS mean (SE)						**	**
Number (%) of patients achieving MCID at Week 24 ^{b,c}	19 (20.4)	28 (32.9)	35 (36.8)*	34 (40.5)*	6 (5.6)	33 (30.8)	36 (33.6)
Change from baseline at Week 52 ^d mean (SE)			-2.2 (0.28)	-2.3 (0.28)		-2.2 (0.24)	-2.2 (0.27)

^aMixed models repeated measures (MMRM) analysis was used to calculate change from baseline.

^bAnalysis of patients with Fatigue NRS ≥ 3 at baseline. SPIRIT-P1: PBO, n=93; ADA, n=85; Q4W, n=95; Q2W, n=84. SPIRIT-P2: PBO, n=108; Q4W, n=107; Q2W, n=107.

^cNonresponder imputation (NRI) was used to impute missing data based on logistic model.

^dMultiple imputation (MI) was used to impute missing data.

*p<0.05 vs PBO; **p<0.001 vs PBO.

Conclusions: In a subset of PsA patients, clinically meaningful improvements in fatigue level were observed following IXE treatment. Fatigue improvement persisted with up to 1 year of IXE treatment.

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Disclosure of Interest: A.-M. Orbai Grant/research support from: Abbvie, Celgene, Eli Lilly, Horizon, Janssen, Novartis, Pfizer, Consultant for: Eli Lilly, Janssen, Novartis, Pfizer, UCB, D. D. Gladman Grant/research support from: Abbvie, Amgen, Celgene, Janssen, Novartis, Pfizer, UCB, Consultant for: Abbvie, Amgen, BMS, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, UCB, H. Goto Grant/research support from: Abbvie, Eli Lilly, Kyowa Hakko Kirin, Consultant for: Abbvie, AYUMI, Chugai, Eisai, Eli Lilly, Janssen, Maruho, Mitsubishi Tanabe, Novartis, Pfizer, Takeda, Speakers bureau: Abbvie, AYUMI, Chugai, Eisai, Eli Lilly, Janssen, Maruho, Mitsubishi Tanabe, Novartis, Pfizer, Takeda, J. Birt Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, C.-Y. Lin Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, T. K. Kvien Grant/research support from: AbbVie, BMS, MSD, Pfizer, Roche, UCB, Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly and Company, Epirus, Hospira, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz, UCB

DOI: 10.1136/annrheumdis-2018-eular.2130