

were on csDMARDs only, 616 (42%) were on first line biologic/targeted synthetic (ts)DMARD therapy, and 172 (12%) were on second line biologic/tsDMARD therapy. The relationship between skin severity and joint activity was statistically significant ( $p < 0.0001$ ) with a correlation of 0.183. Results were similar when adjusting separately for treatment and for duration of PsA and PsO. Greater age, female gender, higher dactylitis count, not achievement of MDA, higher HAQ, and patient reported pain and fatigue affected the relationship.

**Conclusions:** The relationship between skin severity and joint activity is statistically significant and varies by age, gender, MDA, HAQ, and patient reported pain and fatigue. This suggests degree of skin involvement is important to take into account when evaluating PsA patients.

**References:**

- [1] Gottlieb AB, Mease PJ, Mark Jackson J, Eisen D, Amy Xia H, Asare C, Stevens SR: Clinical characteristics of psoriatic arthritis and psoriasis in dermatologists' offices. *J Dermatol Treat* 2006;17:279-287.
- [2] Jones SM, Armas JB, Cohen MG, Lovell CR, Evison G, McHugh NJ: Psoriatic arthritis: outcome of disease subsets and relationship of joint disease to nail and skin disease. *Br J Rheumatol* 1994;33:834-839.
- [3] Cohen MR, Reda DJ, Clegg DO: Baseline relationships between psoriasis and psoriatic arthritis: analysis of 221 patients with active psoriatic arthritis. Department of Veterans Affairs Cooperative Study Group on Seronegative Spondyloarthropathies. *J Rheumatol* 1999;26:1752-1756.

**Acknowledgements:** Corrona, LLC has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, AstraZeneca, BMS, Crescendo, Eli Lilly and Company, Genentech, GSK, Horizon Pharma USA, Janssen, Momenta Pharmaceuticals, Novartis, Pfizer, Roche and UCB.

**Disclosure of Interest:** P. Mease Grant/research support from: Celgene, Novartis, Abbvie, Amgen, BMS, Janssen, Lilly, Pfizer, Sun, UCB, Consultant for: AbbVie, Amgen, BMS, Crescendo, Celgene, Corrona, Demira, Janssen, Lilly, Merck, Novartis, Pfizer, UCB, Sun, Zynerba, Speakers bureau: Abbvie, Amgen, BMS, Celgene, Crescendo, Genentech, Janssen, Novartis, Pfizer, UCB, C. Etzel Consultant for: Merk, Employee of: Corrona, LLC, J. Lisse Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, A. Armstrong Grant/research support from: AbbVie, Janssen, Lilly; speaker's bureau: AbbVie, Lilly, Consultant for: AbbVie, Amgen, Janssen, Merck, Lilly, Celgene, Novartis, and Pfizer, W. Huster Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, S. Rebello Employee of: Corrona, LLC, R. Dodge Employee of: Corrona, LLC, T. Muram Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, S. Al Sawah-Folian Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, M. Murage Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, J. Greenberg Shareholder of: Corrona, LLC, Consultant for: Genentech, Janssen, Novartis and Pfizer, Eli Lilly, Employee of: Corrona, LLC, W. Malatestinic Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company

DOI: 10.1136/annrheumdis-2017-eular.1938

**AB0784 EFFECTIVENESS OF ANTI-TNFS ON DACTYLITIS AND ENTHESITIS IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS FROM THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS REGISTRY**

P.J. Mease<sup>1,2</sup>, R. Singh<sup>3</sup>, K. Douglas<sup>3</sup>, D. Hua<sup>4</sup>, H.J. Litman<sup>4</sup>, C. Karki<sup>4</sup>, J. Griffith<sup>3</sup>. <sup>1</sup>Swedish Medical Center; <sup>2</sup>University of Washington, Seattle; <sup>3</sup>AbbVie, Inc., Abbott Park; <sup>4</sup>Corrona, LLC, Southborough, United States

**Background:** Dactylitis and enthesitis are common disease manifestations encountered in nearly 10-30% of patients with psoriatic arthritis (PsA). Previous clinical trial data suggests that anti-tumor necrosis factors (aTNFs) are effective in controlling dactylitis and enthesitis among PsA patients, however there are limited data from real world studies.

**Objectives:** To evaluate the effectiveness of aTNFs on dactylitis and enthesitis in patients with PsA enrolled in Corrona, a large US observational cohort of patients with PsA and spondyloarthritis.

**Methods:** Adult PsA patients who initiated or were currently on a tTNF at registry enrollment (baseline) between 3/2013-9/2016 and had a 12 month follow-up visit were included. Dactylitis was defined as a non-zero total dactylitis score on a scale 0-20 and enthesitis was defined by a non-zero score on the SPARCC enthesitis index, 0-16. The primary outcome was change in dactylitis and enthesitis scores at 12 months from baseline. Descriptive analysis of patient characteristics at baseline was examined and change in outcomes was evaluated using t-tests.

**Results:** There were 28 patients with dactylitis and 77 patients with enthesitis who met the inclusion criteria. Patients with dactylitis and enthesitis had a mean (SD): age of 48.2 (14.8) and 53.5 (11.5) years, body mass index of 30.8 (6.6) and 31.4 (7.6), disease duration of 9.3 (9.1) and 8.1 (7.7) years, and 28.6% and 45.5% were on methotrexate combination therapy respectively. Patients had a mean clinical disease activity index of 15.1 in both groups, 40.0% and 17.1% were in minimal disease activity, mean (SD): body surface area was 4.4 (4.4) and 5.2 (9.7), pain was 33.1 (29.5) and 43.3 (27.5) on a visual analogue scale (VAS) of 0-100, and more than 80% and 90% of patients had some morning stiffness in the dactylitis and enthesitis groups, respectively. At 12 months from baseline, there were significant improvements in both dactylitis and enthesitis scores in patients with PsA treated with aTNFs (Table).

Table: Primary outcomes in PsA patients on aTNFs at 12 months from baseline

	At enrollment	At 12 month visit	Change in score (enrollment - 12 month visit)	p-value*
Dactylitis Count (0-20)	n=28	n=28	n=28	
Mean (± SD)	2.1 (±1.5)	0.5 (±1.1)	-1.6 (±1.8)	0.001
SPARCC Enthesitis Count (0-16)	n=77	n=77	n=77	
Mean (± SD)	4.1 (±3.2)	1.9 (±2.8)	-2.2 (±3.2)	<0.001

SPARCC: Spondyloarthritis Research Consortium of Canada; \*Calculated based on a t test assessing whether the change in counts differs from 0.

**Conclusions:** In this clinical registry, aTNF therapy significantly improved both dactylitis and enthesitis at 12 months. Further evaluation of secondary outcomes and larger studies with comparator cohorts will further validate the effectiveness of aTNFs in improving the outcomes in PsA patients.

**Acknowledgements:** This study is sponsored by Corrona, LLC. The Corrona, LLC has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, BMS, Crescendo, Eli Lilly and Company, Genentech, GSK, Horizon Pharma USA, Janssen, Momenta Pharmaceuticals, Novartis, Pfizer, Roche and UCB. The design, study conduct, and financial support for the study was provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the abstract.

**Disclosure of Interest:** P. Mease Grant/research support from: Celgene, Novartis, Abbvie, Amgen, BMS, Janssen, Lilly, Pfizer, UCB, Consultant for: Celgene, Corrona, Merck, Novartis, Abbvie, Amgen, BMS, Crescendo, Genentech, Janssen, Lilly, Merck, Pfizer, UCB, Speakers bureau: Abbvie, Amgen, BMS, Crescendo, Genentech, Janssen, Lilly, Novartis, Pfizer, UCB, R. Singh Shareholder of: AbbVie, Inc. Employee of: AbbVie, Inc. K. Douglas Shareholder of: AbbVie, Inc. Employee of: AbbVie, Inc. D. Hua Employee of: Corrona, LLC, H. Litman Employee of: Corrona, LLC, C. Karki Employee of: Corrona, LLC, J. Griffith Shareholder of: AbbVie, Inc. Employee of: AbbVie, Inc

DOI: 10.1136/annrheumdis-2017-eular.1532

**AB0785 CONSISTENT SAFETY PROFILE WITH UP TO 4 YEARS OF APREMILAST TREATMENT: ANALYSIS OF DATA FROM 1493 PATIENTS WITH PSORIATIC ARTHRITIS IN 3 LARGE, PHASE III, LONG-TERM STUDIES**

P.J. Mease<sup>1</sup>, D.D. Gladman<sup>2</sup>, J.J. Gomez-Reino<sup>3</sup>, S. Hall<sup>4</sup>, A. Kavanaugh<sup>5</sup>, E. Lespessailles<sup>6</sup>, G. Schett<sup>7</sup>, M. Paris<sup>8</sup>, L. Teng<sup>8</sup>, J. Wollenhaupt<sup>9</sup>. <sup>1</sup>Swedish Medical Center and University of Washington School of Medicine, Seattle, United States; <sup>2</sup>Toronto Western Research Institute, Toronto, Canada; <sup>3</sup>Hospital Clinico Universitario, Santiago, Spain; <sup>4</sup>Monash University, CabriniHealth, Melbourne, Australia; <sup>5</sup>University of California, San Diego, School of Medicine, La Jolla, United States; <sup>6</sup>University of Orléans, Orléans, France; <sup>7</sup>University of Erlangen-Nuremberg, Erlangen, Germany; <sup>8</sup>Celgene Corporation, Summit, United States; <sup>9</sup>Schön Klinik Hamburg Eilbek, Hamburg, Germany

**Background:** Apremilast (APR), an oral phosphodiesterase 4 inhibitor, regulates immune activity in psoriatic arthritis (PsA) patients. Safety data were pooled from the phase 3 PALACE 1, 2, and 3 studies.

**Objectives:** Evaluate the long-term safety of APR treatment for up to 4 years in patients with active PsA despite prior conventional DMARDs and/or biologics.

**Methods:** Patients were randomized at baseline (1:1:1) to placebo (PBO), APR 30 mg BID (APR30), or APR 20 mg BID (APR20). PBO patients were re-randomized

	APR-Exposure Period*			
	Weeks 0 to ≤52	Weeks >52 to ≤104	Weeks >104 to ≤156	Weeks >156 to ≤208
	APR30 n=721	APR30 n=520	APR30 n=443	APR30 n=401
Patients, n (%)				
≥1 AE	524 (72.7)	316 (60.8)	284 (64.1)	234 (58.4)
≥1 SAE	47(6.5)	35 (6.7)	40 (9.0)	28 (7.0)
AE leading to drug withdrawal	56 (7.8)	13 (2.5)	7 (1.6)	7 (1.7)
Death	0 (0.0)	1 <sup>§</sup> (0.2)	0 (0.0)	2 <sup>¶</sup> (0.5)
AEs in ≥5% of patients, n (%)				
Diarrhea	112 (15.5)	20 (3.8)	12 (2.7)	4 (1.0)
Nausea	108 (15.0)	11 (2.1)	10 (2.3)	3 (0.7)
Headache	75 (10.4)	17 (3.3)	12 (2.7)	7 (1.7)
Upper respiratory tract infection	60 (8.3)	27 (5.2)	24 (5.4)	21 (5.2)
Nasopharyngitis	41 (5.7)	31 (6.0)	20 (4.5)	26 (6.5)
Select marked abnormalities in clinical laboratory parameters, n/m (%)				
Alanine aminotransferase >3x ULN	9/713 (1.3)	2/518 (0.4)	2/442 (0.5)	1/401 (0.2)
Creatinine >1.7x ULN	1/713 (0.1)	0/518 (0.0)	0/442 (0.0)	1/401 (0.2)
Leukocytes <1.5, 10 <sup>9</sup> /L	0/713 (0.0)	0/517 (0.0)	0/442 (0.0)	0/401 (0.0)
Neutrophils <1, 10 <sup>9</sup> /L	2/713 (0.3)	3/517 (0.6)	2/442 (0.5)	2/401 (0.5)
Platelets <75, 10 <sup>9</sup> /L	0/713 (0.0)	0/517 (0.0)	1/441 (0.2)	0/399 (0.0)
Hemoglobin, male <10.5 g/dL, female <8.5 g/dL	5/713 (0.7)	4/517 (0.8)	5/442 (1.1)	5/401 (1.2)

\*Includes all patients who received APR during the time interval relative to the start of APR treatment. <sup>§</sup>Motor vehicle accident on Day 489. <sup>¶</sup>Cerebrovascular accident on Day 1330 in a 69-year-old man, considered unrelated to study drug; patient had history of myocardial infarction, atrial fibrillation, and cerebrovascular accident. <sup>‡</sup>Stroke on Day 1224 in a 59-year-old woman, considered unrelated to study drug; patient had a history of chronic ischemic heart disease, hypertension, alcoholism, and atrial fibrillation. APR30=apremilast 30 mg BID; AE=adverse event; n/m=number of patients with ≥1 occurrence of the abnormality at any time point/number of patients with ≥1 post-baseline value; ULN=upper limit of normal.