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

P.J. Mease¹, D.D. Gladman², E.K. Davenport³, X. Zhou³, B. Guertel⁴, L. Teng⁴, S. Kaura⁴, P. Nash⁵. ¹Swedish Medical Center and University of Washington School of Medicine, Seattle, USA; ²Krembil Research Institute, Toronto Western Hospital, Toronto, Canada; ³RTI Health Solutions, Research Triangle Park; ⁴Celgene Corporation, Summit, USA; ⁵University of Queensland, Brisbane, Australia

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.

Disclosure of Interest: P. Mease Grant/research support from: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Genentech, Janssen, Eli Lilly, Novartis, Pfizer, Roche, UCB, Consultant for: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Genentech, Janssen, Eli Lilly, Novartis, Pfizer, Roche, UCB, Speakers bureau: Abbott, Amgen, Biogen Idec, BMS, Genentech, Janssen, Eli Lilly, Pfizer, UCB, D. Gladman Grant/research support from: AbbVie, Amgen, BMS, Celgene Corporation, Janssen, Novartis, Pfizer, and UCB, Consultant for: AbbVie, Amgen, BMS, Celgene Corporation, Janssen, Novartis, Pfizer, and UCB, E. Davenport: None declared, X. Zhou: None declared, B. Guertel Employee of: Celgene Corporation, L. Teng Employee of: Celgene Corporation, S. Kaura Employee of: Celgene Corporation, P. Nash Grant/research support from: Celgene Corporation

DOI: 10.1136/annrheumdis-2018-eular.3139

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

P.J. Mease¹, B. Lockshin², C. Liu³, E. Siegel⁴, L. Chen⁵, X. Bu⁵, X. Wang⁵, K. Douglas⁵. ¹Swedish Med. Ctr. and Univ. of Washington, Seattle; ²US Dermatology Partners, Rockville; ³Bellevue Dermatology Clinic, Bellevue; ⁴Arthritis and Rheumatism Associates and Georgetown Univ., Rockville; ⁵AbbVie Inc, N Chicago, USA

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.

Results: Of 681 pts enrolled, 513 pts with a confirmed diagnosis of PsA were included in this analysis. PsA diagnosis was established prior to study entry in 404 pts (established pts), while diagnosis was confirmed during the study in 109 pts (suspected pts). In established pts, PsA was first diagnosed in 352 (87.1%) pts by a rheum and 40 (9.9%) pts by a dermatologist. Among suspected pts, 87 (79.8%) and 15 (13.8%) pts were being managed by dermatologist and rheumatologist, respectively. Patient demographics and disease characteristics were comparable between PsA pts enrolled by rheumatologist and dermatologist. Current disease activity and disease burden were also mostly similar between rheumatologist and dermatologist setting (table 1); though pts enrolled in dermatologist setting had higher scores on skin measures and enthesitis. The median (95% CI) time from symptom onset to PsA diagnosis was 1.0 (0.5, 1.1) and 2.6 (1.7, 4.1) years (y) in pts enrolled in rheumatologist and dermatologist setting, respectively ($p < 0.001$). However, the median time to PsA diagnosis was 0.9 (0.5, 1.0) and 1.0 (0.0, 2.0) y in pts diagnosed by rheumatologists and dermatologists, respectively. After PsA diagnosis, the median time to first csDMARD and to first bDMARD was 1.0 and 2.4 y, respectively. Overall, 282 (55.0%) and 354 (69.0%) pts received csDMARDs and bDMARDs, respectively. Treatment with first csDMARD occurred in 106 (20.7%) pts before PsA diagnosis and 176 (34.3%) pts after diagnosis; for first bDMARD, it was 121 (23.6%) and 233 (45.4%) pts, respectively.

Conclusions: The duration from symptom onset to PsA diagnosis was longer in pts enrolled by dermatologists and was similar in pts diagnosed by both rheumatologists and dermatologists. The median time was longer for treatment with first bDMARD compared with first csDMARD. Current disease activity and disease burden highlight the delay in PsA diagnosis and the need for appropriate management of PsA pts, irrespective of clinical specialty setting.

REFERENCE:

- [1] Gladman DD, et al., *Ann Rheum Dis*, 2011; 70:2152–4.

Acknowledgements: AbbVie funded the LOOP study, contributed to its design, and participated in data collection, analysis and interpretation of the data, and in writing, review, and approval of the publication. AbbVie and the authors thank all study investigators for their contributions and the patients who participated in this study. Medical writing: Deepa Venkitaramani, PhD, of AbbVie.

Disclosure of Interest: P. Mease Grant/research support from: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB. Consultant for: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB. Speakers bureau: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB. B. Lockshin Grant/research support from: AbbVie, Abbott, Amgen, Eli Lilly, Janssen, and Sun Pharma. Consultant for: AbbVie, Abbott, Amgen, Eli Lilly, Janssen, and Sun Pharma. Speakers bureau: AbbVie, Abbott, Amgen, Eli Lilly, Janssen, and Sun Pharma. C. Liu Grant/research support from: AbbVie, Speakers bureau: AbbVie, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, Regeneron, and Sanofi Genzyme. E. Siegel Grant/research support from: AbbVie, Amgen, Celgene, Janssen, Lilly, and Sanofi. Consultant for: AbbVie, Amgen, Celgene, Janssen, Lilly, and Sanofi. Speakers bureau: AbbVie, Amgen, Celgene, Janssen, Lilly, and Sanofi. L. Chen Shareholder of: AbbVie, Employee of: AbbVie, X. Bu Shareholder of: AbbVie, Employee of: AbbVie, X. Wang Shareholder of: AbbVie, Employee of: AbbVie, K. Douglas Shareholder of: AbbVie, Employee of: AbbVie

DOI: 10.1136/annrheumdis-2018-eular.1986

AB0948

TUMOUR NECROSIS FACTOR INHIBITORS AND THEIR IMPACT ON DIABETES MELLITUS AMONG PATIENTS WITH PSORIATIC ARTHRITIS

S. Mantravadi^{1,2}, M. George², A. Ogdie². ¹Thomas Jefferson University; ²University of Pennsylvania, Philadelphia, USA

Background: Tumour necrosis factor is a key inflammatory cytokine in the pathogenesis of psoriatic arthritis (PsA) and diabetes mellitus (DM). ^{1,2}Tumour necrosis factor inhibitors (TNFi) have been shown to be associated with a decreased incidence of DM, but it is unknown whether treatment of PsA with TNFi has off-target therapy benefits for patients with DM. ³

Objectives: To determine whether initiation of a TNFi, compared to initiation of methotrexate (MTX) or metformin, results in a decrease in Haemoglobin A1c (HbA1c) in patients with PsA, DM, and elevated HbA1c.

Methods: A retrospective cohort study was conducted in OptumInsight, a de-identified administrative claims database that includes laboratory values for approximately 10% of patients. Data from 2000–2014 was included. We identified patients with PsA and DM (defined by ICD-9CM codes), with an HbA1c ≥ 7 and examined change in HbA1c among new initiators of a TNFi (etanercept, adalimumab, certolizumab, or golimumab), MTX, and metformin (positive control). A baseline period of 12 months prior to the index date was required to capture potential confounders. All patients were required to have one HbA1c in the six months prior to and one HbA1c in the 6 months after drug initiation. We evaluated median

HbA1c change in each group and then assessed statistical differences using the Wilcoxon Rank Sum test (unadjusted). We then used linear regression models to determine the relative differences in HbA1c change using MTX as the reference and adjusted for age, sex, baseline A1c, DM medications, and comorbidities in the baseline period, with clustering to account for multiple new drug initiations per patient.

Results: Among 914 drug initiations in 756 patients with PsA and available HbA1c values, HbA1c was ≥ 7 before 125 (44%) of TNFi initiations, 90 (43%) of MTX initiations, and 233 (55%) of metformin initiations. The average time between baseline and follow-up HbA1c values was 231 days. Median HbA1c change was -0.50 (IQR $-1.30, 0.30$) after TNFi initiation, -0.40 (IQR $-1.50, 0.10$) after MTX initiation, and -0.90 (IQR $-1.80, 0$) after metformin initiation (figure 1). In adjusted analyses, TNFi initiators had a similar decrease in HbA1c compared to MTX initiators, β 0.02 (95%CI: $-0.29, 0.33$). Metformin initiators had a significantly greater change in HbA1c than MTX patients, β -0.43 (95%CI: $-0.72, -0.13$).

Abstract AB0948 – Figure 1

Conclusions: TNFi and MTX initiation lead to a decline in HbA1c by half as much as metformin. Changes in HbA1c were not different among patients initiating TNFi versus MTX.

REFERENCES:

- [1] Coates LC, et al. *Semin Arthritis Rheum* 2016 12;46(3):291–304.
[2] Solomon SS, et al. *Horm Metab Res* 2010;42:115–121.
[3] Solomon D, et al. *JAMA* 2011;305(24):2525–2531.

Disclosure of Interest: S. Mantravadi: None declared, M. George Grant/research support from: Bristol Myers Squibb, A. Ogdie Grant/research support from: Pfizer and Novartis, Consultant for: AbbVie, Bristol Myers Squibb, Lilly, Pfizer, Novartis, and Takeda

DOI: 10.1136/annrheumdis-2018-eular.3550

AB0949

SERUM 25-HYDROXYVITAMIN D STATUS IN PATIENT WITH PSORIATIC ARTHRITIS

S. Tsuji¹, J. Hashimoto¹, T. Noguchi², S. Akita², K. Yachi², S. Ohshima¹, Y. Saeki³, M. Higashiyama⁴. ¹Department of Rheumatology and Allergology; ²Department of Orthopaedic Surgery; ³Department of Clinical Research, NATIONAL HOSPITAL ORGANIZATION, OSAKA MINAMI MEDICAL CENTER, Kawachinagano City, Osaka; ⁴Department of Dermatology, Nissay Hospital, Osaka city, Japan

Background: Vitamin D has been recognised not only in calcium metabolism and bone metabolism but also in the physiological activities of a wide variety of cells, and its deficiency is caused by fractures/falls, osteoporosis and other various disease risks have been reported.

Objectives: To clarify vitamin D satisfaction status of patients with PsA, which is one of spondyloarthritis, by measuring serum 25OHD concentration.

Methods: 180 patients with PsA satisfying CASPAR criteria during the visit to our hospital between August 2016 and June 2017, 125 males, averaging age 54.1 y.o., BMI average 24.2, mean disease duration of PsA and psoriasis were 8.1 years, 19.3 years, respectively. The type of psoriatic arthritis was 79 spondylitis type and 101 peripheral type. MTX was 51.7% as an agent for treating PsA, and the average dose was 8.3 $\pm$ 3.1 mg/week. The number of biologics use was 37.2%. There were 9 cases of osteoporosis and 21 cases of osteopenia, 20 patients who were undergoing treatment for osteoporosis, and all patients were treated with activated VD3. 110 patients (61.1%) had active type VD3 paint applied to psoriasis eruption. The ACPA positive rate was 7.4%, the rheumatoid factor positive was 17.7%, and