SAT0324

CERTOLIZUMAB PEGOL PROVIDES SUSTAINED REMISSION AND MINIMAL DISEASE ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS OVER 4 YEARS' TREATMENT

D. van der Heijde¹, A. Deodhar², O. FitzGerald³, R. Fleischmann⁴, D. Gladman⁵, A. B. Gottlieb⁶, L.C. Coates⁷, B. Hoepken⁸, L. Bauer⁹, L. Peterson⁹, M. Khraishi¹⁰, P. J. Mease¹¹. ¹Leiden University Medical Centre, Leiden, Netherlands; ²Oregon Health and Science University, Portland, OR, USA; ³St Vincent's University Hospital and Conway Institute for Biomolecular Research, University College Dublin, Dublin, Ireland; ⁴University of Texas Southwestern Medical Center, Dallas, TX, USA; ⁵Centre for Prognosis Studies in The Rheumatic Diseases and Krembil Research Institute, Toronto Western Hospital, Toronto, Canada; ⁶Department of Dermatology, New York Medical College at Metropolitan Hospital, New York, NY, USA; ⁷Nuffield Orthopaedic Centre, Oxford, UK; ⁸UCB Pharma, Monheim, Germany; ⁹UCB Pharma, Raleigh, NC, USA; ¹⁰Department of Medicine, Memorial University of Newfoundland, St John's, Canada; ¹¹Swedish Medical Center and University of Washington, Seattle, WA, USA

Background: Disease Activity Index for Psoriatic Arthritis (DAPSA)¹ and the minimal disease activity (MDA) criteria² are instruments recommended for evaluating disease activity in psoriatic arthritis (PsA). The RAPID-PsA trial (NCT01087788) has demonstrated the sustained efficacy of certolizumab pegol (CZP) across the spectrum of PsA symptoms.^{3,4}

Objectives: To report the proportion of CZP-treated patients (pts) achieving DAPSA remission (REM), DAPSA low disease activity (LDA), MDA (fulfilling $\geq 5/7$ MDA criteria), and very low disease activity (VLDA; fulfilling 7/7 MDA criteria) over 216 weeks (wks) in RAPID-PsA.

Methods: RAPID-PsA was double-blind and placebo-controlled to Wk24, dose-blind to Wk48, and open-label (OL) to Wk216. Pts had active PsA and had failed ≥ 1 disease modifying anti-rheumatic drug. Data for pts randomised to CZP at Wk0 (200 mg every 2 wks or 400 mg every 4 wks, following a 400 mg loading dose at Wks0, 2, 4), who continued their assigned dose in the OL period, are presented as observed case and with imputation (figure 1). Outcomes reported are DAPSA (the sum of tender and swollen joint counts [TJC 68; SJC 66], pt global and pain assessment [10 cm visual analogue scale], and C-reactive protein levels [mg/dL]), and pts achieving: 1) DAPSA LDA (DAPSA ≤ 4 and ≤ 14); 2) DAPSA REM (DAPSA ≤ 4); 3) MDA (fulfilling $\geq 5/7$ MDA criteria); and 4) VLDA (fulfilling 7/7 MDA criteria), to Wk216. Pts withdrawing from the study between scheduled visits had their final observed assessment values assigned to the next scheduled visit timepoint.

Results: Of 409 pts randomised; 273 received CZP from Wk0, of whom 248 (90.8%) completed Wk24, 237 (86.8%) completed Wk48, and 183 (67.0%) completed Wk216. The mean (SD) baseline DAPSA was 44.8 (22.9). Of pts completing Wk24, 29.7% (74/249) achieved LDA; 25.3% (63/249) REM; 38.2% (95/249) MDA; and 14.9% (37/249) VLDA. At Wk216, 31.9% (59/185) achieved LDA; 44.3% (82/185) REM; 57.8% (107/185) MDA; and 29.0% (58/183) VLDA (figure 1).

Figure: A) Patients with PsA achieving DAPSA LDA and REM over 4 years' CZP treatment

B) Patients with PsA achieving MDA and VLDA over 4 years' CZP treatment

Data shown for the Randomized Set, for pts on either dose regimen. OC proportions are calculated as the number achieving the target relative to the number of pts assessed at that timepoint. Missing values were imputed using LOCF for DAPSA and NRI for MDA criteria. [a] Number of patients with an observed value at the scheduled visit timepoint; [b] The proportion of pts achieving MDA ($\geq 5/7$ criteria) shown includes those achieving VLDA (7/7 MDA criteria). CZP: certolizumab pegol; DAPSA: Disease Activity Index for Psoriatic Arthritis; DAPSA LDA: DAPSA low disease activity (≤ 4 and ≤ 14); DAPSA remission: DAPSA REM (≤ 4); LOCF: last observation carried forward; MDA: minimal disease activity; NRI: non-responder imputation; OC: observed case; PsA: psoriatic arthritis; pt: patient; VLDA: very low disease activity.

Abstract SAT0324 – Figure 1. A) Patients with PsA achieving DAPSA LDA and REM over 4 years' CZP treatment. B) Patients with PsA achieving MDA and VLDA over 4 years' CZP treatment

Conclusions: A substantial proportion of pts who completed the 4 year study achieved disease inactivity targets: ~75% achieved DAPSA LDA or REM, almost 60% achieved MDA, and half of those also achieved VLDA.

REFERENCES:

- [1] Schoels MM. Ann Rheum Dis 2016;75(5):811–18.
- [2] Coates LC. Ann Rheum Dis 2010;69(01):48–53.
- [3] Mease PJ. Ann Rheum Dis 2016;75:608.
- [4] FitzGerald O. JAAD 2017;76(6):AB264.

Acknowledgements: This study was funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. Editorial services were provided by Costello Medical.

Disclosure of Interest: D. van der Heijde Consultant for: AbbVie, Amgen, Astellas, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Daiichi, Eli Lilly, Galapagos, Gilead, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis, UCB Pharma, Employee of: Director of Imaging Rheumatology B. V., A. Deodhar Grant/research support from: AbbVie, Amgen, Eli Lilly, GlaxoSmithKline, Janssen, Novartis, Pfizer, UCB Pharma, Consultant for: Eli Lilly, Janssen, Novartis, Pfizer, UCB Pharma, O. FitzGerald Grant/research support from: AbbVie, Bristol-Myers Squibb, Janssen, Pfizer, Consultant for: AbbVie, Celgene, Amgen, Eli Lilly, Janssen, Pfizer, UCB Pharma, Speakers bureau: AbbVie, Celgene, Janssen, Novartis, Pfizer, UCB Pharma, R. Fleischmann Grant/research support from: AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, Celgene, Eli Lilly, Genentech, Janssen, MSD Pharmaceuticals, Novartis, Pfizer, Roche, Sanofi-Aventis, UCB Pharma, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Janssen, Novartis, Pfizer, Sanofi-Aventis, D. Gladman Grant/research support from: Abbott, Amgen, Bristol-Myers Squibb, Celgene, Johnson and Johnson, MSD, Novartis, Pfizer, UCB Pharma, Consultant for: Abbott, Bristol-Myers Squibb, Celgene, Johnson and Johnson, MSD, Novartis, Pfizer, UCB Pharma, A. Gottlieb Grant/research support from: Abbott, Acclaris, Actelion, Akros, Amicus, Amgen, Astellas, Baxalta, Beiersdorf, Bristol-Myers Squibb, Canfit, Catabasis, Celgene, Coronado, Crescendo Bioscience, CSL Behring Biotherapies for Life, Dermipor, Dermira, Eli Lilly, Genentech, GlaxoSmithKline, Incyte, Janssen, Karyopharm, KinetaOne, KPI Therapeutics, Levia, Meiji Seika Pharma Co., Merck, Mitsubishi Tanabe, Novartis, Novo Nordisk, Pfizer, Reddy, Takeda, TEVA, UCB Pharma, Vertex, Xenoport, L. Coates Grant/research support from: AbbVie, Janssen, Novartis, Pfizer, Consultant for: Abbott, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, MSD, Novartis, Pfizer, Prothena, Sun Pharma, UCB Pharma, B. Hoepken Employee of: UCB Pharma, L. Bauer Employee of: UCB Pharma, L. Peterson Employee of: UCB Pharma, M. Khraishi Grant/research support from: Abbott, Amgen, Pfizer, Consultant for: Abbott, Amgen, Pfizer, P. Mease Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, Eli Lilly, Novartis, Pfizer, Sun, UCB Pharma, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, Eli Lilly, Novartis, Pfizer, Sun, UCB Pharma, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Genentech, Janssen, Novartis, Pfizer, UCB Pharma

DOI: 10.1136/annrheumdis-2018-eular.2637

SAT0325

COMPARATIVE ANALYSIS OF GENDER DIFFERENCES, HLA-B27 STATUS AND SKIN LESION SEVERITY IN EARLY AXIAL AND PERIPHERAL PSORIATIC ARTHRITIS PATIENTS

E.E. Gubar, E.Y. Loginova, T.V. Korotaeva, S.I. Glukhova, V.A. Nasonova
Research Institute of Rheumatology, Moscow, Russian Federation

Background: Clinical features of axial involvement in psoriatic arthritis (PsA) had been studied before only at advanced stages. Skin lesion severity, HLA-B27 status and gender-specific differences in early PsA patients with axial involvement hadn't been sufficiently studied.

Objectives: To compare clinical features of two early peripheral PsA patient populations – with and without axial involvement.

Methods: 95 patients (pts) (M/F=47/48) with early PsA according to CASPAR criteria were included; all pts had peripheral arthritis for ≤ 2 years; no inflammatory back pain (IBP) pts were specially selected. Mean age 36.5 ± 10.7 years, disease duration 12.2 ± 10.3 mo, disease activity indexes DAS=4.0 $\pm$ 1.4, DAS28=4.2 $\pm$ 1.1, BASDAI=4.5 $\pm$ 1.6 (in pts with axial involvement); patient's global disease activity (PGA) VAS 56.9 $\pm$ 17.1. All pts were evaluated for the presence of inflammatory

back pain (IBP) by ASAS criteria. The examination included X-ray of sacroiliac joints (SIJs) (pelvic radiographs), HLA B27 antigen status; magnetic resonance imaging (MRI) of SIJs was performed in 79 pts, regardless of the presence of IBP, on Signa Ovation 0,35T. Bone marrow oedema on MRI (STIR) was considered as active MRI sacroiliitis (MRI-SI). Radiographic sacroiliitis (R-SI) was considered according to New York criteria (unilateral grade ≥ 3 or bilateral grade ≥ 2). X-ray and MRI results were evaluated by an independent reader. IBP was observed in 63 cases (66.3%), MRI-SI in 28 of 79 (35.4%) examined cases, R-SI in 29 cases (30.5%). Pts were split into two groups (gr.): those with axial involvement (axPsA), that is with IBP and/or R-SI and/or MRI-SI; and those without axial involvement (having only peripheral PsA [pPsA]). The axPsA gr. included 65 (68.4%) cases, the pPsA gr. – 30 (31.6%) cases. Skin lesion severity was evaluated in terms of body surface area (BSA) affected and Psoriasis Area Severity Index (PASI). When BSA was $\geq 3\%$, PASI was calculated. PASI ≥ 11 indicates moderate and severe psoriasis.

Results: The following significant differences were revealed between gr. axPsA and gr. pPsA: **gender-related ones:** in gr. axPsA men-to-women ratio was 60.0% to 40.0%, while in gr. pPsA it was 26.7% to 73.3% ($p=0.003$); **age-related ones:** mean age of gr. axPsA was 33.9 ± 9.6 years, while of gr. pPsA it was 41.7 ± 10.6 years ($p=0.0007$); **in disease duration:** in gr. axPsA it was 10.3 ± 8.7 mo. which was less than gr. pPsA 16.1 ± 11.7 mo. ($p=0.008$); **in HLA-B27 antigen status:** in gr. axPsA it was positive in 47.6% of pts. while in gr. pPsA in 23.3% of pts. ($p=0.02$); **in PGA:** 58.4 ± 17.3 mm in gr. axPsA, and 49.8 ± 16.7 mm in gr. pPsA ($p=0.02$); **in skin lesions' severity:** it was higher in gr. axPsA: BSA median was 3.0 [1.0–9.0] in gr. axPsA and 1.0 [0.2–3.0] in gr. pPsA ($p=0.007$), and PASI median was 15.6 [6.6–55.2] in gr. axPsA and 6.0 [0.0–7.2] in gr. pPsA ($p=0.006$).

Conclusions: Axial involvement in early PsA patients is significantly more frequent in males and in pts with positive HLA-B27 antigen status. Axial involvement is associated with high patient-reported disease activity and severe skin lesion. These findings may have a positive impact on diagnosis of axial disease, as well as on the selection of the best therapeutic strategy.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2385

SAT0326

DURATION OF REMISSION AND MINIMAL DISEASE ACTIVITY AFTER STARTING AND DISCONTINUATION OF BIOLOGIC (B) DMARDs IN EARLY PSORIATIC ARTHRITIS PATIENTS TREATED ACCORDING TO TREAT-TO-TARGET STRATEGY (RESULTS OF AN OPEN-LABEL REMARCA STUDY)

E. Loginova, T. Korotaeva, E. Gubar, S. Glukhova, E. Nasonov. *Nasonova Research Institute of Rheumatology, Moscow, Russian Federation*

Background: The main goal of treat-to-target (T2T) strategy in psoriatic arthritis (PsA) is achievement of remission (REM) or minimal disease activity (MDA). There is limited data concerning the duration of REM/MDA after starting and discontinuation of bDMARDs in early (E) PsA patients (pts).

Objectives: to investigate the timing and duration of REM/MDA after starting and discontinuation of bDMARDs therapy in EPsA pts treated according to T2T strategy.

Methods: 34 (M-18/F-16) pts with active EPsA according to the CASPAR criteria non-responder to methotrexate (MTX) subcutaneous treatment, bDMARD-naïve were included; mean age 38 ± 11 years, PsA duration 12 ± 10 months (mon.), psoriasis duration 89.8 ± 91.1 mon., median Disease Activity index for Psoriatic Arthritis (DAPSA) 33.55 [28.34–41.77]. All pts started bDMARDs: Adalimumab (21 pts), Certolizumab pegol (3 pts), Etanercept (2 pts), Ustekinumab (8 pts) $\pm$ MTX. The median duration of bDMARDs treatment was 9 [6.5–15], Min 3 mon. – Max 24 mon. The bDMARDs treatment was stopped due to an individual inefficiency, loss of efficacy or non-medical reasons. At baseline and every 3 mon. all pts underwent assessment of PsA activity by DAPSA and MDA criteria (tender joint count ≤ 1 , swollen joint count ≤ 1 , PASI ≤ 1 or BSA ≤ 3 , patient pain global assessment VAS ≤ 15 , patient's global disease activity VAS ≤ 20 , HAQ ≤ 0.5 , enthesitis count ≤ 1). The proportion of pts who achieved REM by DAPSA ≤ 4 and MDA (5 of 7 cutpoints) at least once, as well as timing and duration of REM/MDA after starting and cessation of bDMARDs were performed. Pts reports about a flare coming, close to the scheduled time of assessment, was taken into account. M $\pm$ SD, Me [Q75; Q50], (%) were calculated. All $p < 0.05$ were considered to indicate statistical significance.

Results: By the 24 mon. of the study REM by DAPSA and MDA was reached at least once by 27 (79%) and 28 (82%) out of 34 pts, accordingly. Mean timing of REM by DAPSA and MDA after starting of bDMARDs was 5.8 ± 3.2 and 4.0 ± 1.9 mon., accordingly. During the observation 19 out of 27 pts (70.4%) had stopped bDMARDs due to different reasons. 8 out of 27 pts (29.6%) continued the treatment and had REM according to DAPSA by the end of the study. After cessation of bDMARDs flares by DAPSA were seen in 12 out of 19 pts (63.2%) with the mean duration of REM 5.8 ± 2.3 mon. (Fig 1.). The loss of MDA was seen in 12 out of 20 pts (60%) with the mean duration of MDA 6.2 ± 3.0 mon. Pts reports about

the time of PsA symptoms flares was 3.5 ± 3.4 mon. 5 out of 34 pts (15%) loss the efficacy after 12.0 ± 4.7 mon. of bDMARDs treatment.

Abstract SAT0326 – Figure 1. Dynamics of DAPSA after starting and discontinuation of bDMARDs therapy in EPsA.

Conclusions: Most EPsA pts treated with bDMARDs according to T2T strategy achieved REM and MDA within 5 mon. Flares after bDMARDs discontinuation within 6 mon were found in more than a half of pts. according to PsA activity indices and within 3 mon. by pts reports. REM and flare timing after bDMARDs therapy discontinuation indicate that further studies concerning optimal management PsA pts by bDMARDs are needed.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.3245

SAT0327

BASELINE CHARACTERISTICS AND REASONS FOR APREMILAST PRESCRIPTION IN A LARGE ITALIAN COHORT OF PSORIATIC ARTHRITIS PATIENTS

E.G. Favalli¹, C. Zuccaro², M. Biggioggero¹, C. Selmi³, R. Bucci⁴, F. D'Onofrio⁵, G. Carlino⁶, L. Santoro⁷, A. Semeraro⁸, S. Monti⁹, D. Mazzotta¹⁰, F. Atzeni¹¹, R. Caporali⁹, F. Iannone¹². ¹Department of Rheumatology, Gaetano Pini Institute, Milano; ²Hospital Outpatient clinic of Rheumatology, ASL BR, Brindisi; ³Rheumatology, Humanitas Research Hospital, BIOMETRA Department, University of Milan, Milano; ⁴Rheumatology Hospital Unit, A.O.U. "O.O.R.R. Foggia"; ⁵UOC Reumatologia Universitaria, University of Foggia, Foggia; ⁶Rheumatology Service, ASL Lecce – DSS Casarano and Gallipoli, Lecce; ⁷Rheumatology Service, DSS4 Barletta ASL BT Andria, Andria; ⁸UO of Rheumatology, ASL Taranto, Taranto; ⁹Department of Rheumatology, University of Pavia, IRCCS Policlinico San Matteo Foundation, Pavia; ¹⁰Hospital Outpatient clinic of Rheumatology, ASL BR, Brindisi, Brindisi; ¹¹Rheumatology, University of Messina, Messina; ¹²DETO-Rheumatology Unit, University of Bari, Bari, Italy

Background: There are no real-world data for the profiling of patients with psoriatic arthritis (PsA) receiving the phosphodiesterase-4 inhibitor apremilast.

Objectives: To retrospectively evaluate the baseline characteristics and the reasons for apremilast prescription in a large Italian multicenter cohort of PsA cases (Real-life APremilast for Psoriatic arthritis Evaluation Registry, RAPPER).

Methods: Data were retrospectively extracted from the RAPPER registry which includes all PsA cases treated with apremilast in 11 Italian tertiary rheumatology centres between January 2017 and December 2017. Descriptive analysis of baseline characteristics of study population included demographics, previous treatments before apremilast, pattern of PsA involvement, disease activity indices, and prevalence of comorbidities (computed by the Rheumatic Disease Comorbidity Index [RDCI]). Reasons for apremilast choice were also analysed.

Results: We studied 97 patients with PsA (61% women; mean [standard deviation, SD] age 56.7 ± 11.9 years; mean disease duration 10 ± 13.1 years) who received apremilast as first-line targeted disease modifying drug (51.5%) or after the failure of at least one biologic agent (48.5%). In 75%, 33%, 11%, and 63% of patients there were articular (57% asymmetric oligoarthritis; mean Disease Activity in Psoriatic Arthritis [DAPSA] 22.55 ± 11.55), enthesal (mean Leeds Enthesitis Index [LEI] 2.63 ± 1.42), axial (mean Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] 6.02 ± 2.40), and skin/ungueal (mean body surface area [BSA] 1.71 ± 3.44) involvement, respectively. Two thirds (64%) of patients had at least one comorbidity (mean RDCI 1.20) and the prevalence of conditions is reported in table 1. The main reasons for apremilast prescription were contraindication to biologic agents (66%), lack of poor prognostic factors (35%), comorbidities (34%),